

**GUIDE TO THE DEPOSIT OF MICROORGANISMS
UNDER THE BUDAPEST TREATY**

Filing Instructions
for the 1999 Edition

The 1999 edition of the Budapest Guide has been updated and reprinted in its entirety and therefore completely replaces the 1998 version, which should be discarded.

April 2000

**Guide to the Deposit of
Microorganisms
under the Budapest Treaty**



**WORLD INTELLECTUAL PROPERTY ORGANIZATION
GENEVA**

NOTE

The Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (hereinafter referred to as the “Budapest Treaty” or the “Treaty”) was concluded on April 28, 1977, and entered into force on August 19, 1980.

The fundamental principle of the Budapest Treaty is that all States party to it recognize a deposit made in any one of certain culture collections (“international depositary authorities”) as sufficient for the purposes of their own patent procedure. The Treaty and the Regulations thereunder establish rules on deposits with international depositary authorities, storage and furnishing of samples of deposited microorganisms.

The purpose of this Guide is to present in a systematic manner information on the procedures and requirements concerning the deposit of microorganisms and to give practical advice to persons depositing microorganisms for patent purposes, on the one hand, and to anyone wishing to obtain samples of such microorganisms, on the other hand.

Following an introduction and a summary of the main features of the Budapest Treaty, the Guide is divided into two parts dealing, respectively, with the general requirements of the Treaty as they relate to the deposit of microorganisms and the furnishing of samples thereof (Part I), and the specific requirements of each of the international depositary authorities and of each of the industrial property offices of the States party to the Budapest Treaty as well as the European Patent Office (Part II). Appendices to the Guide give a checklist of the points to be attended to when depositing microorganisms or requesting the furnishing of samples (Appendix 1); the full text of the Budapest Treaty and the Regulations (Appendix 2); copies of the models of forms used under the Budapest Treaty and the Regulations (Appendix 3); and standards for the packaging of microorganisms for transport by air (Appendix 4).

It is hoped that this Guide will assist depositors of microorganisms, international depositary authorities, industrial property offices and in general all concerned with the protection of biotechnological inventions to better understand and take advantage of the system of deposit of microorganisms provided for under the Budapest Treaty.

With the exception of Part II, which has been prepared by the International Bureau, the text of the Guide has been written by Dr. Ivan Bousfield, Executive Director and Curator of the National Collections of Industrial and Marine Bacteria Ltd., Aberdeen, United Kingdom, to whom WIPO hereby expresses its sincere appreciation.

Geneva, April 2000

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- (i) General
- (ii) Information on IDAs

Australia (AU)

Australian Government Analytical Laboratories (AGAL)

Belgium (BE)

Belgian Coordinated Collections of Microorganisms (BCCM™)

Bulgaria (BG)

National Bank for Industrial Microorganisms and Cell Cultures (NBIMCC)

Canada (CA)

Bureau of Microbiology at Health Canada (BMHC)

China (CN)

China Center for Type Culture Collection (CCTCC)

China General Microbiological Culture Collection Center (CGMCC)

Czech Republic (CZ)

Czech Collection of Microorganisms (CCM)

Note: The two-letter code after each country name conforms with WIPO Standard ST.3 (Recommended Standard Two-Letter Code for the Representation of Countries).

France **(FR)**

Collection nationale de cultures de micro-organismes (CNCM)

Germany **(DE)**

Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH (DSMZ)

Hungary **(HU)**

National Collection of Agricultural and Industrial Microorganisms (NCAIM)

Italy **(IT)**

Advanced Biotechnology Center (ABC)

Collection of Industrial Yeasts DBVPG

Japan **(JP)**

National Institute of Bioscience and Human-Technology (NIBH)

Latvia **(LV)**

Microbial Strain Collection of Latvia (MSCL)

Netherlands **(NL)**

Centraalbureau voor Schimmelcultures (CBS)

Republic of Korea **(KR)**

Korean Cell Line Research Foundation (KCLRF)

Korean Collection for Type Cultures (KCTC)

Korean Culture Center of Microorganisms (KCCM)

Russian Federation **(RU)**

National Research Center of Antibiotics (NRCA)

Russian Collection of Microorganisms (VKM)

Russian National Collection of Industrial Microorganisms (VKPM), GNII Genetika

Slovakia **(SK)**

Culture Collection of Yeasts (CCY)

Spain (ES)

Colección Española de Cultivos Tipo (CECT)

United Kingdom (GB)

Culture Collection of Algae and Protozoa (CCAP)

European Collection of Cell Cultures (ECACC)

International Mycological Institute (IMI)

National Collection of Type Cultures (NCTC)

National Collection of Yeast Cultures (NCYC)

National Collections of Industria, Food and Marine Bacteria (NCIMB)

United States of America (US)

Agricultural Research Service Culture Collection (NRRL)

American Type Culture Collection (ATCC)

Section E: Requirements of Industrial Property Offices
of States Party to the Budapest Treaty and of
Intergovernmental Industrial Property Organizations

Introduction

- (i) General
- (ii) Information on Industrial Property Offices

AT	Austria
AU	Australia
BE	Belgium
BG	Bulgaria
CA	Canada
CH	Switzerland
CN	China
CU	Cuba
CZ	Czech Republic
DE	Germany
DK	Denmark
EE	Estonia
ES	Spain
FI	Finland
FR	France
GB	United Kingdom
GR	Greece
HR	Croatia
HU	Hungary
IE	Ireland
IL	Israel
IS	Iceland
IT	Italy
JP	Japan
KR	Republic of Korea

LI	Liechtenstein
LT	Lithuania
LV	Latvia
MC	Monaco
MD	Republic of Moldova
NL	Netherlands
NO	Norway
PH	Philippines
PL	Poland
PT	Portugal
RO	Romania
RU	Russian Federation
SE	Sweden
SG	Singapore
SI	Slovenia
SK	Slovakia
TJ	Tajikistan
TR	Turkey
TT	Trinidad and Tobago
UA	Ukraine
US	United States of America
YU	Yugoslavia
ZA	South Africa
AP	African Regional Industrial Property Organization (ARIPO)
EA	Eurasian Patent Organization (EAPO)
EP	European Patent Office (OEB)

APPENDIX 1: CHECKLISTS OF POINTS TO BE ATTENDED TO WHEN
DEPOSITING MICROORGANISMS AND REQUESTING SAMPLES UNDER THE
BUDAPEST TREATY

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INTRODUCTION TO THE BUDAPEST TREATY

(a) Deposit of Microorganisms for the Purposes of Patent Procedure

(i) Disclosure and the Requirement for Deposit

1. A fundamental requirement of patent law is that the details of an invention must be fully disclosed to the public. For disclosure to be adequate, an invention must be described in sufficient detail to permit a person skilled in the art to repeat the effect of the invention: in other words, the disclosure should enable the average expert with access to the appropriate facilities to reproduce the invention for himself. Disclosure is normally achieved by means of a written description supplemented where necessary by drawings. However, inventions involving the use of new microorganisms (i.e., those not available to the public) present problems of disclosure in that repeatability often cannot be ensured by means of a written description alone. In the case of an organism isolated from soil, for instance, and perhaps “improved” by mutation and further selection, it would be virtually impossible to describe the strain and its selection sufficiently to guarantee another person obtaining the same strain from soil himself. In such a case, the microorganism itself might be considered to be an essential part of the disclosure. Moreover, if the microorganism was not generally available to the public, the written disclosure of the invention might be held to be insufficient. This line of reasoning led to the industrial property offices in an increasing number of countries either requiring or recommending that the written disclosure of an invention involving the use of a new microorganism be supplemented by the deposit of the microorganism in a recognized culture collection. The culture collection would then make the microorganism available to the public at the appropriate point in the patenting procedure.

(ii) Need for a Uniform International Deposit System

2. Although by the early 1970s the depositing of microorganisms in culture collections for patent purposes had become fairly common, there was no uniform system of deposit, or, perhaps more importantly, of *recognition* of deposit. Most countries requiring or recommending deposit required it to be made in a “recognized” collection, but the minimum criteria to be met by such “recognized” collections were vague and ill defined. In most cases, “recognized” probably equated with “internationally known.” The culture collections for their part, when confronted with the variety of national patent laws, were often unsure of how to proceed in respect of the furnishing of samples to requesting parties. Lack of firm guidelines led some collections to allow the depositor almost complete control over the furnishing of samples of his microorganism, believing this to be the surest way of protecting themselves from the danger of releasing a sample illegitimately.

3. Faced with the above-mentioned uncertainties, many patent applicants saw no alternative but to deposit the same microorganism in several collections in different countries to guard against the possibility of any of their applications failing on the grounds of insufficient disclosure. Clearly this practice was wasteful, time-consuming and sometimes expensive, and, taken to its logical conclusion, would have resulted in applicants depositing the microorganism in every country in which they wished to file a patent application referring to that microorganism. In order to obviate the need for such multiple deposits, therefore, the Government of the United Kingdom proposed, in 1973, that the World Intellectual Property

Organization (WIPO) should study the possibilities of one deposit serving the purposes of all the deposits that would otherwise be needed. This proposal was adopted by the Governing Bodies of WIPO.

(iii) The Budapest Treaty

4. In 1974, the Director General of WIPO convened a Committee of Experts to discuss the possibilities of international cooperation over the deposit of microorganisms for patent purposes. The essence of the solution prepared in discussions of this Committee was that certain culture collections should be recognized as depositary authorities and that a deposit made with any one of them should be recognized as valid for patent purposes by all the countries in which protection for the relevant invention was sought. The Committee of Experts also found that the conclusion of a treaty would be necessary to put this proposed solution into effect. At two further sessions in 1975 and 1976 the Committee of Experts examined drafts prepared by the International Bureau of WIPO of a Treaty and Regulations on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure. A third draft of this Treaty and Regulations served as a basis for the deliberations of a Diplomatic Conference, convened by the Director General of WIPO, organized by him in cooperation with the Government of Hungary, and held in Budapest from April 14 to 28, 1977. The Diplomatic Conference, which was attended by representatives of 29 States¹ members of the Paris Union for the Protection of Industrial Property and observers from two non-member States² of the Paris Union, the Interim Committee of the European Patent Organisation, and 11 non-governmental international organizations,³ adopted a treaty with the title “Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure,” together with Regulations under the Treaty.

5. The Budapest Treaty came into effect in 1980 when it had been ratified or acceded to by the requisite minimum number (five) of States. The Regulations under the Budapest Treaty were modified on January 20, 1981, by the Assembly of the Budapest Union at its second extraordinary session. The said modifications entered into force on January 31, 1981.

¹ Australia, Austria, Bulgaria, Czechoslovakia, Denmark, Egypt, Finland, France, German Democratic Republic, Germany (Federal Republic of), Hungary, Indonesia, Italy, Japan, Mexico, Netherlands, Norway, Philippines, Poland, Portugal, Romania, Senegal, Soviet Union, Spain, Sweden, Switzerland, United Kingdom, United States of America, Yugoslavia.

² Democratic People’s Republic of Korea, Pakistan.

³ Committee of National Institutes of Patent Agents (CNIPA), European Federation of Agents of Industry in Industrial Property (FEMIP), Council of European Industrial Federations (CEIF), International Association for the Protection of Industrial Property (AIPPI), International Chamber of Commerce (ICC), International Federation of Patent Agents (FICPI), International Federation of Pharmaceutical Manufacturers Associations (IFPMA), Pacific Industrial Property Association (PIPA), Union of European Patent Attorneys and Other Representatives Before the European Patent Office (UNEPA), Union of Industries of the European Community (UNICE), World Federation for Culture Collections (WFCC).

(b) Main Features of the Budapest Treaty

(i) International Depositary Authorities and Recognition of Single Deposit

6. Under the Treaty, certain culture collections are recognized as “international depositary authorities” (IDAs). Any Contracting State which allows or requires the deposit of microorganisms for the purposes of patent procedure must recognize, for those purposes, a deposit made in any IDA, wherever that IDA may be. Similarly, if any intergovernmental industrial property organization (e.g., the European Patent Organisation) files a formal declaration with the Director General of WIPO to the effect that, for its own patent purposes, it accepts the provisions of the Treaty and the Regulations, then it too must recognize a deposit made in any IDA.

7. Any culture collection can become an IDA provided that it has been formally nominated by the Contracting State on whose territory it is located and that that Contracting State has furnished solemn assurances that the collection complies and will continue to comply with the requirements of the Treaty and the Regulations. The most important of these are that the IDA will be available on the same terms to any depositor, that it will accept and store microorganisms deposited with it for the full period specified by the Treaty, and that it will furnish samples of deposited microorganisms only to those entitled to receive them. An intergovernmental industrial property organization which has filed the declaration referred to in paragraph 6 similarly may furnish assurances in respect of a culture collection located on the territory of one of its member States.

(ii) Deposit and Furnishing of Samples

8. The Regulations under the Treaty lay down in detail the procedures which depositors and IDAs must follow, the duration of storage of deposited microorganisms (at least 30 years or five years after the most recent request for a sample, whichever is later), and the mechanisms for the furnishing of samples. The Regulations do not address the timing of deposit, however; this is left entirely to the relevant national law. So, to a large extent, are the timing and conditions of furnishing of samples. Provision is made for samples to be furnished at any time to the depositor, to anyone having the depositor’s written authorization, and to any “interested” industrial property office (i.e., one dealing with a patent application concerning the deposited microorganism and which provides the IDA with a declaration to that effect), but in all other cases national law determines when, to whom and under what conditions samples are to be furnished. However, because IDAs may not be familiar with the national laws of different countries, the Regulations require that a third party requesting a sample from an IDA must make his request on a form on which the relevant industrial property office certifies that he is entitled to receive a sample of that particular microorganism. Alternatively, the industrial property office may, from time to time, notify IDAs of the accession numbers of those microorganisms referred to in patents granted and published by it, in which case such microorganisms become available to anyone without the need for certification.

(iii) Safeguard of Deposits

9. The Treaty and Regulations make various provisions to guard against the loss and consequent non-availability of deposited microorganisms. Thus the IDA must have the

expertise and facilities necessary to keep the microorganism viable and uncontaminated throughout the storage period required by the Treaty. If for any reason an IDA is no longer able to furnish samples of a microorganism, a new deposit of the same organism can be made and can benefit from the date of deposit of the original. If for any reason an IDA ceases to function as such, the Treaty provides for the microorganisms deposited with it to be transferred to another IDA.

(iv) Meaning of the Term “Microorganism”

10. The term “microorganism” is not defined in the Treaty so that it may be interpreted in a broad sense as to the applicability of the Treaty to microorganisms to be deposited under it. Whether an entity technically is or is not a microorganism matters less in practice than whether deposit of that entity is necessary for the purposes of disclosure and whether an IDA will accept it. Thus, for example, tissue cultures and plasmids can be deposited under the terms of the Treaty, even though they are not microorganisms in the strict sense of the word.

PART I: GENERAL REQUIREMENTS FOR DEPOSIT AND FURNISHING OF SAMPLES

Section A: Making the Original Deposit

(a) Obligations of the Depositor

(i) Universal Requirements

11. When making an original deposit under the Budapest Treaty, the depositor must comply with Rules⁴ 6.1(a) and 6.3(a). Rule 6.1(a) specifies the minimum information which the depositor must supply to the IDA when he sends his microorganism for deposit; Rule 6.3(a) lists the additional requirements which the IDA may ask the depositor to meet in respect of its own administrative procedures.

12. According to Rule 6.1(a):

“The microorganism transmitted by the depositor to the international depositary authority shall...be accompanied by a written statement bearing the signature of the depositor and containing:

(i) an indication that the deposit is made under the Treaty and an undertaking not to withdraw it for the period specified in Rule 9.1;”

The period specified in Rule 9.1 is five years after the most recent request for a sample, and in any case at least 30 years. It is important to realize that a deposit made under the Treaty cannot be cancelled during this period, either by the depositor or the IDA, regardless of whether a patent is eventually granted. This applies even if patent applications relating to the deposit are abandoned or withdrawn.

13. Rule 6.1(a) continues:

“(ii) the name and address of the depositor;

(iii) details of the conditions necessary for the cultivation of the microorganism, for its storage and for testing its viability and also, where a mixture of microorganisms is deposited, descriptions of the components of the mixture and at least one of the methods permitting the checking of their presence;”

This provision ensures that the IDA is given sufficient information to enable it to handle the microorganism correctly. The instructions referring to mixed cultures are intended to ensure that a positive viability statement (see paragraphs 33 to 39) is not issued unless all the components of the co-culture have been shown to be viable.

⁴ Whenever the words “Article(s)” or “Rule(s)” are used in this Guide, they mean Article(s) or Rule(s) of the Budapest Treaty, unless otherwise specified.

14. Rule 6.1(a) continues:

“(iv) an identification reference (number, symbols, etc.) given by the depositor to the microorganism;”

The wording of this clause is sometimes misinterpreted. It does not mean that the depositor should have identified his microorganism in a taxonomic sense; it simply means the designation by which he refers to the organism. The “identification reference” may be a name, of course, but equally it may be merely a strain designation or even just a laboratory code number.

15. Rule 6.1(a) concludes:

“(v) an indication of the properties of the microorganism which are or may be dangerous to health or the environment, or an indication that the depositor is not aware of such properties.”

The provisions of Rule 6.1(a) are fairly obvious requirements which are intended to ensure that the IDA is aware that the deposit is being made under the Budapest Treaty and is able to deal with the microorganism in the laboratory correctly and safely. Nevertheless, the requirements of Rule 6.1(a) are mandatory and may not be varied either by the depositor or the IDA. Indeed if the depositor does not comply with them all, the IDA is obliged by Rule 6.4(b) (see paragraph 29) to ask him to do so before it can accept the deposit.

16. Scientific description and/or taxonomic designation. Whereas Rule 6.1(a) lists the indications that must be contained in the written statement sent by the depositor to the IDA, Rule 6.1(b) states:

“It is strongly recommended that the written statement...should contain the scientific description and/or proposed taxonomic designation of the deposited microorganism.”

Since this Rule is not a requirement but an exhortation, compliance with it is not mandatory. Moreover, if the depositor does decide to submit a scientific description and/or proposed taxonomic designation, he need not do so at the time of deposit. Rule 8.1(a) permits the communication of this information at some later date, and also provides for the amendment of any description/designation indicated previously. The contents of such a communication are regulated by Rule 8.1(b), which states:

“Any such later indication or amendment shall be made in a written communication, bearing the signature of the depositor, addressed to the international depositary authority and containing:

- (i) the name and address of the depositor;
- (ii) the accession number given by the said authority;
- (iii) the scientific description and/or proposed taxonomic designation of the microorganism;

(iv) in the case of an amendment, the last preceding scientific description and/or proposed taxonomic designation.”

When making such a communication, the depositor may ask the IDA to provide him with an attestation containing the information referred to in Rule 8.1(b)(i) to (iv) and the date on which the IDA received the communication (Rule 8.2). The IDA is obliged to meet such a request, but is entitled to charge a fee for so doing (Rule 12.1(a)(ii)).

(ii) Requirements of IDAs

17. As well as the foregoing requirements, the Regulations permit the IDA to impose on the depositor certain conditions of its own. The extent of these conditions is governed by Rule 6.3(a), which states:

“Any international depositary authority may require:

(i) that the microorganism be deposited in the form and quantity necessary for the purposes of the Treaty and these Regulations;”

This provision allows the IDA to require that cultures of microorganisms are submitted to it in a particular state, e.g., on agar slants, in liquid suspension, lyophilized, etc.; that a specified number of replicates is provided; that cultures should not be below a specified minimum titre; and so on.

18. Rule 6.3(a) continues:

“(ii) that a form established by such authority and duly completed by the depositor for the purposes of the administrative procedures of such authority be furnished;”

This means the accession form and any other form routinely used by the IDA and obtainable from it.

19. Rule 6.3(a) continues:

“(iii) that the written statement referred to in Rule 6.1(a) or 6.2(a) be drafted in the language, or in any of the languages, specified by such authority, it being understood that such specification must at least include the official language or languages indicated under Rule 3.1(b)(v);”

This is a provision permitting a Japanese IDA, for example, to ask for information to be supplied to it in Japanese. Rule 3.1(b)(v) refers to the official language(s) of the institution specified in the communication required under Article 7(1) of the Treaty from the Contracting State or intergovernmental industrial property organization nominating that institution for the acquisition of IDA status. Rule 6.2(a) refers to the statement required from the depositor in the event of a new deposit, and is dealt with in Section B of this Guide.

20. Rule 6.3(a) continues:

“(iv) that the fee for storage referred to in Rule 12.1(a)(i) be paid;...”

Rule 12.1(a)(i) permits the IDA to charge the depositor for storing his microorganism in accordance with the Treaty. However, Rule 12.1(b) requires this fee to cover the whole duration of storage; thus it must be a once-and-for-all payment.

21. Rule 6.3(a) concludes:

“(v) that, to the extent permitted by the applicable law, the depositor enter into a contract with such authority defining the liabilities of the depositor and the said authority.”

This provision allows the IDA to make the kind of contractual arrangements with the depositor that would be usual under the laws of contract of the IDA's own country.

22. The provisions of Rule 6.3(a) allow the IDA to apply its normal in-house administrative and technical requirements to the internal processing of deposits. It is entirely a matter of choice for the IDA whether it demands any or all of the requirements permitted under Rule 6.3(a), but if it does, then it must so inform the International Bureau of WIPO (Rule 6.3(b)). The depositor must comply with any such requirements to ensure acceptance of his microorganism. These requirements are dealt with in Section D of this Guide.

(b) Obligations of the IDA

(i) Kinds of Microorganisms Accepted

23. The communication to the Director General of WIPO from a Contracting State or an intergovernmental industrial property organization, referred to in Article 7 and Rule 3, nominating a culture collection for the acquisition of IDA status must specify the kinds of microorganisms that the culture collection will accept for deposit under the Budapest Treaty (Rule 3.1(b)(iii)). From the time of its acquisition of IDA status that culture collection is obliged to accept all such microorganisms for deposit (subject to Rule 6.4(a)(ii) and (iii)—see paragraphs 26 and 27).

(ii) Extension or Limitation of the Kinds of Microorganisms Accepted

24. If the IDA subsequently wishes to limit or extend the list of kinds of microorganisms it accepts, it must do so by notifying the modified list to the Contracting State or intergovernmental industrial property organization under whose assurances it has acquired IDA status. That State or organization in turn must formally notify the Director General of WIPO of the withdrawal of its declaration of assurances either entirely or in respect only of certain kinds of microorganisms (Article 8(2)(a), Rule 4.2(a) and (b)) or of the extension of the list of kinds of microorganisms accepted (Rule 3.3). The changes then come into effect at the earliest three months from the date of notification in the case of a limitation of the list of the kinds of microorganisms accepted (Rule 4.2(c)) and immediately after publication by the International Bureau of WIPO in the case of an extension (Rule 3.3, Article 7(2)(b)) of such

list. In either case, the State or organization may specify a later effective date than that just mentioned.

(iii) Refusal to Accept a Microorganism

25. An IDA may refuse to accept a microorganism sent to it for deposit only in certain circumstances, which are specified in Rule 6.4(a). This Rule states:

“(a) the international depositary authority shall refuse to accept the microorganism and shall immediately notify the depositor in writing of such refusal and of the reasons therefor:

(i) where the microorganism is not of a kind of microorganism to which the assurances furnished under Rule 3.1(b)(iii) or 3.3 extend;”

Although the reason for this provision may appear self-evident, it is important to note that the IDA is not merely entitled, but is obliged to refuse such a microorganism.

26. Rule 6.4(a) continues:

“(ii) where the properties of the microorganism are so exceptional that the international depositary authority is technically not in a position to perform the tasks in relation to it that it must perform under the Treaty and these Regulations;”

This provision covers the situation where, on the face of it, the microorganism should be of a kind which the IDA accepts, but where in fact the IDA clearly is unable to handle it. An example would be a strain of an otherwise “acceptable” species, which either naturally or because of genetic manipulation was too difficult for the IDA to cultivate.

27. Rule 6.4(a) concludes:

“(iii) where the deposit is received in a condition which clearly indicates that the microorganism is missing or which precludes for scientific reasons the acceptance of the microorganism.”

This provision again relates to a microorganism that in normal circumstances would be accepted by the IDA. It would apply, for example, where the receptacle containing the culture had been broken in transit, thereby making recovery of the microorganism in an uncontaminated state impossible.

28. Rule 6.4(a) specifies the only circumstances in which an IDA may legitimately refuse to accept a microorganism for deposit, other than by virtue of continued non-compliance by the depositor with the requirements for deposit. Refusal by the IDA in any other case is in contravention of its obligations under the Treaty and could lead to its losing its status as an IDA (Article 8, Rules 4 and 5).

(iv) Acceptance of the Original Deposit

29. The requirements which the IDA must observe when accepting a microorganism for deposit are laid down in Rule 6.4(b), (c) and (d). Rule 6.4(b) and (c) states:

“(b) Subject to paragraph (a), the international depositary authority shall accept the microorganism when all the requirements of Rule 6.1(a) or 6.2(a) and Rule 6.3(a) are complied with. If any of those requirements are not complied with, the international depositary authority shall immediately notify the depositor in writing of that fact and invite him to comply with those requirements.

“(c) When the microorganism has been accepted as an original or new deposit, the date of that original or new deposit, as the case may be, shall be the date on which the microorganism was received by the international depositary authority.”

Thus the IDA is obliged to ensure that the depositor has met all the mandatory requirements for deposit (see paragraphs 11 to 22) before it can accept the microorganism. However, deferment of formal acceptance (as opposed to refusal) pending the depositor's compliance with all his obligations does not prejudice the date of deposit. Except in the case of a conversion of a deposit made outside the Budapest Treaty under Rule 6.4(d) (see paragraphs 30 and 31), the date of deposit is held to be the date on which the IDA physically receives the microorganism, even though all procedural requirements for acceptance may not have been met on that date.

(v) Conversion of Deposits Made Outside the Budapest Treaty

30. Rule 6.4(d) allows for a deposit originally made outside the provisions of the Treaty and before the culture collection became an IDA to be converted to a deposit made under the Treaty. This Rule states:

“The international depositary authority shall, on the request of the depositor and provided that all the requirements referred to in paragraph (b) are complied with, consider a microorganism, deposited before the acquisition by such authority of the status of international depositary authority, to have been received, for the purposes of the Treaty, on the date on which such status was acquired.”

The requirements for converting an existing deposit into a “Budapest deposit” are essentially the same as those which must be met when making an original deposit under the Treaty, except that the microorganism itself, of course, will already have been sent and received. However, it must be realized that when a deposit is converted under Rule 6.4(d), for the purposes of the Treaty the date of deposit is held to be the date on which the culture collection acquired IDA status, not the earlier date on which the collection physically received the microorganism. It is important that this “artificial” date of deposit be borne in mind in relation to the filing dates of patent applications referring to the deposited microorganism. Following an “understanding” reached by the Assembly of the Budapest Union (in 1981 and in 1990), the depositor may request that a deposit made with an IDA, but outside the scope of the Budapest Treaty, be converted into a Budapest Treaty deposit. Furthermore, according to such “understanding” in such a case, the date recognized for the purposes of the Treaty as the date of deposit is determined by the applicable national law. In practice this means that

whereas some industrial property offices may recognize the date on which the IDA received the microorganism as the date of deposit, others may recognize only the date of receipt by the IDA of the request for conversion. Depositors should bear this in mind and consider any effects it may have on patent applications or patents referring to the converted deposit.

31. Conversion is a useful facility because it means that an earlier non-Budapest Treaty deposit can be accorded the international recognition which it might not otherwise command. Conversion, for example, is essential for the recognition by the Japanese Patent Office of any non-Budapest Treaty deposit made outside Japan, regardless of its previous availability. At present, however, only the original depositor (or his successor in title) can convert a deposit. In all other cases, a separate deposit of the same organism must be made under the Treaty. Moreover, some IDAs will not agree to the conversion of deposits previously made for purely scientific purposes because of the constraints which the Budapest Treaty system might impose on the hitherto unrestricted distribution of samples. In such cases, separate deposit of the microorganism under the Treaty is again necessary.

(vi) Issuance of Receipt

32. Having received and accepted a microorganism for deposit (or having converted an existing deposit), the IDA must notify the depositor of this fact by issuing to him an official receipt in respect of that deposit (Rule 7.1). The receipt must be made out on the so-called “international form” BP/4 (see Appendix 3). This form is one of four “international forms,” a model of which has been established by the Director General of WIPO and the Budapest Union Assembly (Rule 7.2(a)). Wherever the Regulations specify the use of an “international form” by IDAs, such use is mandatory. The receipt must be signed by an authorized representative of the IDA (Rule 7.2(c)) and must contain the specific information required by Rule 7.3 which states:

“Any receipt referred to in Rule 7.1 and issued in the case of an original deposit shall indicate that it is issued by the depositary institution in its capacity of international depositary authority under the Treaty and shall contain at least the following indications:

- (i) the name and address of the international depositary authority;
- (ii) the name and address of the depositor;
- (iii) the date of the original deposit as defined in Rule 6.4(c);
- (iv) the identification reference (number, symbols, etc.) given by the depositor to the microorganism;
- (v) the accession number given by the international depositary authority to the deposit;
- (vi) where the written statement referred to in Rule 6.1(a) contains the scientific description and/or proposed taxonomic designation of the microorganism, a reference to that fact.”

The receipt is a very important communication for it constitutes a written attestation by the IDA that the microorganism in question was deposited with it on a particular date, was accepted by it, and was assigned a particular accession number. Moreover, the receipt together with a positive first viability statement (see paragraphs 33 to 39) provide documentary evidence that a deposit meeting the requirements of the Budapest Treaty has been made. Also, by virtue of the obligations imposed on IDAs by the Treaty, these documents are a presumptive indication that the deposited microorganism will be kept in storage and samples thereof will be furnished according to the requirements of the Treaty. Any Contracting State may demand a copy of the receipt (Article 3(1)(b)). (It should be noted in this connection, however, that, notwithstanding the provisions of Article 3(2) and the assurances furnished under Article 7(1)(a) in respect of the IDA, certain industrial property offices may require an additional declaration from the IDA as to the permanence and availability of the deposit.)

(vii) Viability Testing and Statement

33. As soon as possible after receiving a microorganism for deposit, the IDA must test the viability of the microorganism (Rule 10.1(i)) and must inform the depositor in writing of the results of the test (Rule 10.2(a)(i)), using mandatory “international form” BP/9. The obligations placed on IDAs in respect of the viability testing of an original deposit are laid down in Rule 10.1, which states:

“The international depositary authority shall test the viability of each microorganism deposited with it:

(i) promptly after any deposit referred to in Rule 6 or any transfer referred to in Rule 5.1;”

Rule 5.1 refers to the transfer of microorganisms from a defaulting to a substitute IDA and is dealt with in Section B of this Guide.

34. Rule 10.1 continues:

“(ii) at reasonable intervals, depending on the kind of microorganism and its possible storage conditions, or at any time, if necessary, for technical reasons;”

This provision, while requiring the IDA to pay attention to the viability testing of a microorganism during the storage period, nevertheless leaves the frequency of such testing to the professional judgment of the IDA.

35. Rule 10.1 concludes:

“(iii) at any time, on the request of the depositor.”

This provision acknowledges the right of the depositor to demand on any particular occasion evidence of the viability of his deposit.

36. Viability Statement. The circumstances in which an IDA must provide a written statement in respect of an original deposit are given in Rule 10.2(a), which states:

“The international depositary authority shall issue a statement concerning the viability of the deposited microorganism:

- (i) to the depositor, promptly after any deposit referred to in Rule 6 or any transfer referred to in Rule 5.1;
- (ii) to the depositor, on his request, at any time after the deposit or transfer;
- (iii) to any industrial property office, other authority, natural person or legal entity, other than the depositor, to whom or to which samples of the deposited microorganism were furnished in conformity with Rule 11, on his or its request, together with or at any time after such furnishing of samples.”

This provision entitles anyone who has received a sample of the microorganism also to receive a viability statement, if he so wishes. In such a case, and in the case of Rule 10.2(a)(ii), above, the viability statement must refer to the most recent viability tests (Rule 10.2(c)).

37. The contents of the viability statement are laid down by Rule 10.2(b), which states:

“The viability statement shall indicate whether the microorganism is or is no longer viable and shall contain:

- (i) the name and address of the international depositary authority issuing it;
- (ii) the name and address of the depositor;
- (iii) the date referred to in Rule 7.3(iii) or, where a new deposit or a transfer has been made, the most recent of the dates referred to in Rules 7.4(iii) and 7.5(iii);”

The two last mentioned dates are the dates of receipt by the IDA of a new deposit or transferred deposit, respectively.

38. Rule 10.2(b) continues:

- “(iv) the accession number given by the said authority;
- (v) the date of the test to which it refers;
- (vi) information on the conditions under which the viability test has been performed, provided that the said information has been requested by the party to which the viability statement is issued and that the results of the test were negative.”

This last provision enables the recipient of the viability statement to check, in the event of a negative result, that the IDA has carried out the viability test correctly. The IDA is entitled to charge for viability statements issued in respect of an original deposit, except for that issued to

the depositor immediately after deposit or where the recipient is an industrial property office (Rules 10.2(e) and 12.1(a)(iii)).

39. Viability testing is an extremely important part of the depositing procedure under the Budapest Treaty since the whole point of deposit is to ensure that viable samples of the microorganism are made available at the appropriate time and under the requisite conditions to those entitled. The test carried out immediately after deposit is particularly important because it determines in effect the validity of the date of deposit. Accordingly, the viability statement reporting the result of this test is a very important document. If it reports a negative result, and if all subsequent viability statements report similarly negative results, then even though all procedural requirements may have been met in respect of the deposit, the original date of deposit is lost (see paragraph 67). If, on the other hand, the first viability statement reports a positive result, then, in the event of the microorganism subsequently being lost and in the absence of any later positive statements, it is the key to the recognition of the original date of deposit vis à vis any replacement (Article 4(1)(d); see paragraph 66).

(viii) Storage of Microorganisms

40. Having accepted a microorganism for deposit, tested its viability and issued the receipt and viability statement, the IDA is obliged to maintain the microorganism according to the provisions of Rule 9, which states:

“9.1 Duration of the Storage

“Any microorganism deposited with an international depositary authority shall be stored by such authority, with all the care necessary to keep it viable and uncontaminated, for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism was received by the said authority and, in any case, for a period of at least 30 years after the date of the deposit.”

This provision is intended to ensure the permanence of the deposit and in effect simply obliges the IDA to do what would be expected of any culture collection in order to minimize the loss of deposited microorganisms.

41. Rule 9 continues:

“9.2 Secrecy

“No international depositary authority shall give information to anyone whether a microorganism has been deposited with it under the Treaty. Furthermore, it shall not give any information to anyone concerning any microorganism deposited with it under the Treaty except to an authority, natural person or legal entity which is entitled to obtain a sample of the said microorganism under Rule 11 and subject to the same conditions as provided in that Rule.”

This provision is intended to ensure that the deposit of a microorganism remains secret until any patent application referring to it has been published. However, by linking the furnishing of information to the provisions of Rule 11 (see paragraphs 87 to 96), which govern the furnishing of samples, Rule 9.2 relieves the IDA of any obligation to ascertain for itself

whether publication has taken place. (In practice, there are certain exceptions to this; see paragraphs 92 and 104.)

(c) Guidelines for Making the Original Deposit

(i) General

42. Subsections (a) and (b), above, have listed and explained the general requirements, obligations and procedures which must be observed by the depositor and the IDA when an original deposit is being made under the Budapest Treaty. The purpose of this subsection is to offer practical guidance and suggestions to prospective depositors so that timely and trouble-free deposits may be ensured.

(ii) Problems to Be Avoided

43. Last Minute Deposits. Making a deposit under the Budapest Treaty should be quite straightforward, but problems can and do occur. Most of these arise because the depositor has not left enough time for any unexpected difficulties to be put right. It cannot be emphasized too strongly that however good the intentions of the depositor may be, the industrial property office will recognize only the actuality of the deposit. This actuality is the physical receipt by the IDA of a viable sample of the microorganism. Thus, although in principle a microorganism being sent for deposit need not in most cases reach the IDA until the filing date (or priority date, as the case may be) of the corresponding patent application, in practice the depositor should begin the depositing procedure soon enough to allow for any possible delays or mishaps. Some delays can be anticipated, of course. If, say, the deposit is to be made with a foreign IDA, any import or quarantine regulations should be borne in mind. For instance, it may take several weeks, or even months, to import certain cell-lines and viruses into the United States of America (see Section D of this Guide). However, it is the possibility of unexpected delays that makes depositing at the last minute a risk not worth taking in view of the likely consequence for the patent application itself. None of the following common situations causes a problem if the microorganism has been sent for deposit in good time; all pose a serious threat to the last-minute deposit.

44. Postal Delays. Sometimes the microorganism sent for deposit simply fails to arrive at the IDA in time, either because the package has been mailed too late or because of abnormal delays in the postal system. It should also be noted that the postal authorities in some countries will not accept packages containing certain classes of microorganisms transmitted by airmail (see Appendix 4) and will destroy them on receipt. Usually, an IDA is able to advise a prospective foreign depositor whether it can accept his microorganism sent by airmail.

45. Customs Delays. Microorganisms sent for deposit in IDAs abroad often must be transmitted by air freight. Delays frequently occur because depositors have provided insufficient shipping information to allow the smooth passage of the package through the customs authorities in the country of destination (see Appendix 4).

46. Damaged Packages. Sometimes depositors do not pack the vessels containing their microorganisms adequately, with the result that the vessels may be broken in transit, rendering

the microorganism irrecoverable from the package in an uncontaminated state. In such a case, the IDA will refuse to accept the deposit (Rule 6.4(a)(iii)). If the deposit has been made at the last minute, it may be too late to send a replacement. Prospective depositors should note that the packaging of microorganisms for transmission through the overseas mail and by air freight is governed by the regulations of the Universal Postal Union and the International Air Transport Association, respectively (see Appendix 4).

47. Non-viability. Sometimes a microorganism sent for deposit proves to be non-viable when tested by the IDA, necessitating the depositor to send a replacement sample. Such a replacement cannot be treated as a new deposit under the provisions of Article 4 because a positive viability statement was not issued in respect of the original sample (see paragraphs 67 and 68). Thus the replacement must be treated as an original deposit in its own right, which means that the earliest date of deposit is the date on which the IDA receives the replacement sample, not the date on which it received the first sample. If the first sample was sent for deposit at the last minute, the replacement sample may not reach the IDA in time. (It should be borne in mind in this connection that, depending on the kind of microorganism, viability testing may take some time. Thus for most bacteria, fungi, yeasts, algae and protozoa, viability testing usually takes two to five days, for animal cell-lines a week or slightly longer is normal and for animal viruses and plant tissue cells, up to a month is not unusual (see Section D of this Guide).)

48. It is essential to recognize the difference between a new deposit in the sense of Article 4 (see paragraphs 65 to 68) and a replacement deposit as described above, and to realize that if a microorganism is found by the IDA from the outset to be non-viable, the original date of deposit cannot be applied to any replacement.

49. Unacceptable Microorganisms. Occasionally an IDA finds that a microorganism sent to it is not one of the kinds which it accepts under the Treaty, and thus it refuses the deposit (Rule 6.4(a)(i)). Again, if the deposit is being made at the last minute, it may be too late to send the microorganism to another IDA that will accept the deposit.

50. Lack of Communication. Last-minute deposits usually occur through lack of forethought on the part of the depositor or his patent agent, or through lack of communication between the two. And even when the microorganism itself is sent in good time, lack of communication between depositor and agent can cause confusion and delay. In such cases, the date of deposit is not usually jeopardized, but the depositing procedure is made unnecessarily complicated and time-consuming. Thus, for example, the depositor (who is often a scientist with little knowledge of patent procedure) may be told simply to ensure that he sends his microorganism to the IDA by a certain date, without being adequately briefed about the relevant administrative and legal requirements. Consequently, deposits sometimes arrive not only late but also lacking sufficient information to enable the IDA to process them. Furthermore, it is often forgotten that the Treaty speaks always of the depositor and that, unless instructed otherwise, the IDA will communicate only with him. If requested, most IDAs will send copies of receipts and viability statements to both the depositor and his agent, which avoids the common problem of depositors not realizing the importance of the receipt and viability statement and the need to furnish them as evidence of deposit.

51. Problems can also arise when patent agents are inadequately briefed by depositors about possible technical or legal difficulties with their microorganism, with the result that IDAs may

be confronted with situations about which they should have been forewarned. There has been at least one case where the patent agent had all the administrative procedures in hand, only to find that the depositor had told neither him nor the IDA that the microorganism had to be handled under special conditions to which the IDA did not have immediate access.

52. Communication between a patent applicant and his patent agent is always considered vital in the drafting of the patent application and in its filing. It is equally essential in the depositing of microorganisms for patent purposes.

(iii) Guide to Procedures

53. The problems and pitfalls described in paragraphs 43 to 52 can largely be avoided if prospective depositors adhere to the following three simple guidelines:

- start the deposit procedure in good time;
- ensure that adequate briefing is received from the patent agent about administrative and legal requirements;
- ensure that the patent agent is briefed about the kind of microorganism and about any possible technical problems there may be with it.

This being said, the following points about practical procedures should be observed.

54. Acceptability of the Microorganism. The depositor should ensure that the IDA he has chosen is able and empowered to accept for deposit the kind of microorganism to be submitted. If there are likely to be technical problems, he should advise the IDA in advance.

55. IDA Requirements and Forms. The depositor should check the administrative and technical requirements of the IDA (Rule 6.3(a)) and should ask for the appropriate forms.

56. Information. The depositor should give all the information asked for on the forms and should ensure that it is correct, and that it is expressed in one of the official languages of the IDA. It is generally recognized that many depositors will not be familiar with the details of the Budapest Treaty and Regulations and thus may not be fully aware of all their obligations in respect of them. Therefore, the forms which the depositor is asked to fill in are so designed that, by completing them correctly, he automatically provides all the information required of him by the Regulations (in particular, Rule 6.1(a)) and by the IDA itself. (These forms vary to some extent between IDAs but they all follow a similar general pattern.) Nevertheless, deposit forms are not infrequently returned to IDAs only partially completed or containing incorrect information, thus leading to unnecessary delays.

57. Identity of Depositor. It should be made clear whether the person sending the microorganism is himself the depositor or whether he is acting on behalf of the organization employing him. In the case of the latter, the deposit form should be signed by an authorized official of that organization and it should be made clear to whom the IDA should send any official notifications.

58. Patent Agent. If the depositor's patent agent is likely to be communicating with the IDA, the depositor should inform the IDA, otherwise it may withhold information until it has ascertained the agent's right to receive it. In particular, the depositor should tell the IDA if he wishes copies of the receipt and viability statement to be sent to his patent agent.

59. Form and Quantity of the Microorganism. The depositor should ensure that he meets the requirements of the IDA as to the form and quantity of the microorganism to be deposited (Rule 6.3(a)(i)).

60. Advance Information. Although Rule 6.1(a) states that the microorganism should be accompanied by a written statement (the completed deposit form), in practice it is often helpful to an IDA to receive information in advance of the microorganism itself, so that arrangements can be made to deal with the deposit promptly. This is particularly helpful if, say, a special growth medium containing unusual ingredients has to be prepared by the IDA.

61. Date of Deposit. Notwithstanding paragraph 60, the depositor should bear in mind that the date of deposit is the date on which the microorganism is actually received by the IDA. Therefore, in an emergency (which should not arise, of course, if the depositor is following these guidelines), priority should be given to ensuring that the IDA receives the microorganism itself. However, in such a case the depositor should remember that without the written information, the IDA may not be in a position to test the viability of the microorganism.

62. Authenticity Checks. Depending on its policy and on the kind of material being deposited, an IDA may or may not prepare subcultures for eventual distribution as samples of the deposited microorganism. Thus in the case of cell-lines and naked plasmids, for instance, the depositor is usually required to supply sufficient material for the IDA to distribute direct (see also paragraph 59). On the other hand, for bacteria, yeasts, moulds, etc., it is more usual for the IDA to distribute its own preparations. In this case, many IDAs will ask the depositor to check the authenticity of their preparations (a normal practice of culture collections). The depositor is not obliged by the Treaty to check these preparations, but he is well-advised to do so to ensure that the material sent out by the IDA will in fact correspond to the claims in the patent application.

63. Official Communications. The depositor should expect to receive an official receipt and viability statement from the IDA and should be aware of their importance and of the fact that he may be required to furnish them as evidence of deposit. Technically, the receipt should be issued first but in practice, where the viability test takes only a few days, many IDAs find it more convenient to await the result of this test and then send out the receipt and viability statement together. If asked, most IDAs will communicate the accession number and date of deposit by telephone or telex when they have accepted the deposit. However, it must be remembered that these communications are unofficial and have no standing under the Treaty.

64. Conversions. If an existing deposit is being converted to one made under the Budapest Treaty (Rule 6.4(d)), the depositor should first inform the IDA of the accession number of the microorganism and obtain confirmation that the conversion is, in fact, permissible (if it is not, he will have to make another deposit). He should then attend to the points contained in paragraphs 55, 56, 58, 62 and 63, above).

Section B: Making a New Deposit

(a) Circumstances in Which a New Deposit May Be Made

65. Article 4 of the Treaty states:

“(1)(a) Where the international depositary authority cannot furnish samples of the deposited microorganism for any reason, in particular,

(i) where such microorganism is no longer viable, or

(ii) where the furnishing of samples would require that they be sent abroad and the sending or the receipt of the samples abroad is prevented by export or import restrictions, that authority shall, promptly after having noted its inability to furnish samples, notify the depositor of such inability, indicating the cause thereof, and the depositor, subject to paragraph (2) and as provided in this paragraph, shall have the right to make a new deposit of the microorganism which was originally deposited.

“(b) The new deposit shall be made with the international depositary authority with which the original deposit was made, provided that:

(i) it shall be made with another international depositary authority where the institution with which the original deposit was made has ceased to have the status of international depositary authority...or discontinues...the performance of its functions in respect of deposited microorganisms;

(ii) it may be made with another international depositary authority in the case referred to in subparagraph (a)(ii).”

These provisions are intended to ensure, as far as possible, the continued availability of a deposited microorganism in the event of the IDA not being in a position to furnish samples. In this way, the depositor's patent rights are not jeopardized by circumstances that are not of his making and which are beyond his control. It should be noted, however, that according to Article 4(2) these provisions cannot be applied to microorganisms previously transferred to another IDA, unless that IDA is also unable to furnish samples.

(b) Requirements to Be Met

(i) Statement by the Depositor

66. Article 4(1) continues:

“(c) Any new deposit shall be accompanied by a statement signed by the depositor alleging that the newly deposited microorganism is the same as that originally

deposited. If the allegation of the depositor is contested, the burden of proof shall be governed by the applicable law.”

The contents of the signed statement which the depositor must submit with his new deposit are laid down in Rule 6.2, and may be summarized thus (the following is a summary, not a quotation, of Rule 6.2):

(i) where the new deposit is being made with a different IDA, all the indications required under Rule 6.1(a) (see paragraphs 12 to 15);

(ii) the reason for making the new deposit, a statement alleging that the microorganism being submitted is the same as that deposited previously, and an indication of the date on which notification was received from the IDA of its inability to furnish samples (or, as the case may be, the date of publication of the fact that the IDA has lost its status or discontinued its function--Article 4(1)(e); see paragraph 70);

(iii) the most recent scientific description and/or proposed taxonomic designation submitted to the IDA in respect of the previous deposit. (Rule 6.2(c) defines “previous deposit” as either the latest of a succession of earlier new deposits, or the original deposit, as the case may be.)

This signed statement must be accompanied by a copy of the receipt of the previous deposit and a copy of the most recent positive viability statement.

(ii) Date of Deposit

67. Article 4(1) continues:

“(d) Subject to subparagraphs (a) to (c) and (e), the new deposit shall be treated as if it had been made on the date on which the original deposit was made where all the preceding statements concerning the viability of the originally deposited microorganism indicated that the microorganism was viable and where the new deposit was made within three months after the date on which the depositor received the notification referred to in subparagraph (a).”

This subparagraph is central to the concept of continuity of deposit in that it allows the original date of deposit to stand, regardless of the actual date of the new deposit, provided that this latter date falls within the stated three-month time limit.

68. It should be noted that, as mentioned earlier (see paragraphs 39 and 47), the original date of deposit can be applied to a new deposit only if at least one positive viability statement had been issued in respect of the previous deposit. Article 4 does not apply to replacements for deposits that have never been shown to be viable.

(iii) Time Limit

69. The exact dates that circumscribe the three-month time limit are calculated according to Rule 12**bis**.2, which states:

“When a period is expressed as one month or a certain number of months, computation shall start on the day following the day on which the relevant event occurred, and the period shall expire in the relevant subsequent month on the day which has the same number as the day on which the said event occurred, provided that if the relevant subsequent month has no day with the same number the period shall expire on the last day of that month.”

Thus if the depositor receives notification from the IDA on, say, January 15, he must make his new deposit no later than April 15; or if he receives notification on, say, January 31, the new deposit must be made no later than April 30. (The same formula is applied, *mutatis mutandis*, when calculating time periods expressed in years (Rule 12**bis**.1).)

70. This three-month time limit does not begin until the depositor has received notification from the IDA of its inability to furnish samples, except where the IDA has ceased to function as such or has lost its status (Article 4(1)(b)(i)) and has not notified the depositor of this fact. In this case, Article 4(1)(e) states that if the IDA has not notified the depositor within six months of the publication by the International Bureau of WIPO of its loss of status, the three-month time limit starts from the date of that publication. However, in practice Article 4(1)(e) should not need to be invoked since, in the event of loss of status or discontinuance of function by the IDA, the Contracting State is required to ensure the transfer of all deposits to another IDA and to ensure that the defaulting IDA notifies depositors (Rule 5.1; see paragraph 84).

(iv) Receipt and Viability Statement

71. Having received and accepted a new deposit, the IDA must test its viability and must issue to the depositor a receipt and viability statement. The latter is identical with that which would be issued in the case of an original deposit (see paragraphs 36 to 38), but the receipt (Rule 7.4), which must be made out on “international form” BP/5, is not. Indications in Rule 7.4(i) to (v) are the same as in the receipt for an original deposit (see paragraph 32), except that they refer instead to “new deposit,” but Rule 7.4 goes on to state:

“(vi) an indication of the relevant reason and the relevant date as stated by the depositor in accordance with Rule 6.2(a)(ii);”

This refers to the reason for making the new deposit and the date on which the depositor received notification of the inability of the IDA to furnish samples.

72. Rule 7.4 continues:

“(vii) where Rule 6.2(a)(iii) applies, a reference to the fact that a scientific description and/or a proposed taxonomic designation has/have been indicated by the depositor;”

Rule 6.2(a)(iii) refers to the last description/designation submitted in respect of the previous deposit.

73. Rule 7.4 concludes:

“(viii) the accession number given to the previous deposit....”

Unless the new deposit is being made with another IDA, the accession number is likely to be the same as that accorded the previous deposit.

74. If the new deposit is being made with another IDA, the receipt must also give the name and address of the IDA with which the previous deposit was made, although Rule 7.4 does not mention this. When the IDA issues a receipt for a new deposit it must send with it to the depositor copies of the receipt and of the last positive viability statement issued in respect of the previous deposit.

(c) Guidelines for Making a New Deposit

75. If the original date of deposit is to be retained, a viable sample of the newly deposited microorganism must have been received by the IDA no later than the last day of the three-month time limit referred to in Article 4(1)(d) (see paragraph 69). If a viable sample is not received until later, the earliest date of deposit that can be applied to the new deposit is the date on which it was actually received by the IDA. Since loss of the original date of deposit can have serious implications for any patents or applications relating to the particular microorganism, timely action by the depositor when making a new deposit is just as important as when making an original deposit. New deposits made at the last minute are subject to the same risks as are last-minute original deposits (see paragraphs 43 to 49).

76. Most of the suggestions and guidelines discussed in Section A in respect of original deposits are equally applicable to new deposits, but the depositor should also bear the following points in mind when making a new deposit.

77. Notification from the IDA. The depositor should be aware of the significance of a notification from the IDA that it can no longer furnish samples and he should act promptly when he receives it. He should, of course, immediately note the date on which he received the notification and from it calculate the latest date by which any new deposit must be made.

78. Possibility of Transfer. If the IDA is unable to furnish samples because of loss of status or discontinuance of function, the depositor should ascertain (if the IDA has not so informed him) whether his deposited microorganism(s) will be transferred under the aegis of the Contracting State to another IDA in accordance with Rule 5.1(a)(i) (see paragraph 54). If this is to be the case, the right to make a new deposit under Article 4 does not exist (Article 4(2)).

79. Deposit with a Different IDA. If the new deposit is to be made with another IDA, the depositor should ensure that the IDA he chooses will accept his microorganism and he should determine its administrative and technical requirements (see Section D of this Guide), since they may differ from those of the original IDA. However, the depositor has the right to make a new deposit in another IDA only in the case of discontinuance or loss of status (Article 4(1)(b)(i)) or because of export/import restrictions (Article 4(1)(b)(ii)).

80. Identity of the New Deposit. The depositor should take care to ensure that the microorganism he is submitting as a new deposit is the same as that deposited previously, since there is always the possibility of the allegation he makes under Article 4(1)(c) being contested.

81. Statement. Unless the forms from the IDA provide space for it, the depositor should ensure that he has appended a signed statement giving the reason for making a new deposit, the date on which he received notification from the IDA of its inability to furnish samples, and a declaration that the microorganism he is submitting is the same as that previously deposited (Article 4(1)(c) and Rule 6.2(a)(ii)). Some IDAs use WIPO model forms BP/2 and BP/3 (see Appendix 3) for new deposits, which ask for these indications. In such cases, a separate statement is not necessary.

82. Additional Documentation. The depositor should remember that, in addition to the appropriate forms and declaration, he must also submit to the IDA (a) a copy of the receipt for the previous deposit, (b) a copy of the latest positive viability statement issued in respect of the previous deposit, and, if applicable, (c) the latest scientific description/taxonomic designation sent to the IDA in respect of the previous deposit.

(d) Transfer of Deposited Microorganisms

(i) Reasons for Transfer

83. Although they are not, strictly speaking, new deposits, it is appropriate to deal here with the case of deposited microorganisms which are necessarily transferred from one IDA to another. This situation can arise as a consequence of any of the following:

- the IDA temporarily or permanently ceases to carry out its functions in respect of the microorganisms deposited with it;
- the Contracting State or intergovernmental industrial property organization which originally furnished the assurances (Article 6(1)) leading to the IDA acquiring its status withdraws those assurances with the result that the status of the IDA is terminated (Article 8(2)).
- the IDA fails to meet its obligations under the Treaty and Regulations with the result that a Contracting State or intergovernmental industrial property organization successfully petitions the Budapest Union Assembly to terminate or limit the status of the IDA (Article 8(1));
- the IDA loses its status as a consequence of the Contracting State or intergovernmental industrial property organization which furnished the assurances in respect of it under Article 6(1) ceasing to be a party to the Treaty (Article 17(4)) or ceasing to recognize the provisions of the Treaty (Article 9(4)), respectively.

Except in the case of the last of these reasons, which inevitably must be absolute, the foregoing can apply either to all the microorganisms deposited with the IDA or only to certain kinds.

(ii) Obligations of the Contracting State

84. In the event of any of the foregoing, the Contracting State or intergovernmental industrial property organization which furnished the assurances under Article 6(1) is obliged by Rule 5.1 to ensure the prompt transfer of all affected deposits and all relevant files, etc., to another IDA. The State or intergovernmental industrial property organization must also ensure, as far as possible, that the defaulting IDA notifies all affected depositors of such transfers. In these circumstances, the State or the organization decides on the substitute IDA to which deposits are to be transferred, but the depositor may, if he so wishes, ask the defaulting IDA to send, in addition, a sample of any of his deposits and copies of any relevant files, etc., to another IDA. In this case, however, he must bear the expenses of any such additional transfer himself (Rule 5.1(e)).

(iii) Obligations of the Substitute IDA

85. The substitute IDA must issue to the depositor a receipt in respect of any microorganism transferred to it under Rule 5.1 and, after testing their viability, a viability statement. The viability statement is identical with that which would be issued in the case of the original or new deposit, but the contents of the receipt in the case of a transferred deposit (which must be made out on “international form” BP/6) are governed by Rule 7.5. This Rule requires the following particulars:

- “(i) the name and address of the international depositary authority;
- (ii) the name and address of the depositor;
- (iii) the date on which the transferred sample was received by the international depositary authority (date of transfer);
- (iv) the identification reference...given by the depositor to the microorganism;
- (v) the accession number given by the international depositary authority;
- (vi) the name and address of the international depositary authority from which the transfer was effected;
- (vii) the accession number given by the international depositary authority from which the transfer was effected;
- (viii) where the written statement referred to in Rule 6.1(a) or 6.2(a) contained the scientific description and/or proposed taxonomic designation of the microorganism, or where such scientific description and/or proposed taxonomic designation was/were indicated or amended under Rule 8.1 at a later date, a reference to that fact.”

(iv) Position of the Depositor

86. Transfer of deposits in the case of loss of status or cessation of function of the IDA occurs in circumstances over which the depositor has no control, and, therefore, his active

participation in the process is minimal. He should, however, be aware that it may be necessary, depending on the applicable patent procedure, for him to notify the new accession number to any industrial property office with which he has filed an application referring to the original deposit (Rule 5.1(c)). It might be prudent for him to do this in any case. Furthermore, it should be noted that Rule 5.1 requires the Contracting State or intergovernmental industrial property organization to ensure the transfer of deposits “to the fullest extent possible.” There is thus no absolute guarantee that transfer of a particular deposit would in fact be effected. Therefore, when the depositor is notified by the IDA of its inability to furnish samples (as he must be under Article 4) because of loss of status or cessation of function, it is in his own interest to ascertain from the IDA whether his deposits will be transferred according to Rule 5.1. If the answer is negative, he can exercise his right under Article 4(1)(b)(i) to make new deposits with another IDA.

Section C: Furnishing of Samples

(a) General Conditions for Requesting Samples

87. The whole point of depositing a microorganism for patent purposes is to make it available to entitled parties according to the requirements of patent law. The purpose of this section is to inform depositors of the general conditions under which samples of their deposit will be furnished under the Budapest Treaty and to advise third parties of the requirements they must comply with when requesting a sample. This section should be read with reference to Section E, which gives the requirements of individual countries as to the furnishing of samples of deposited microorganisms.

88. It is widely acknowledged that IDAs cannot be expected to be familiar with the patent laws of countries throughout the world. Thus to require an IDA to judge for itself whether a particular third party is legally entitled to receive a sample of a particular deposit is generally considered to be undesirable. Many industrial property authorities also consider it unreasonable to expect an IDA to ascertain from the relevant industrial property office (which it may not even know) the legitimacy of every request for a sample. Therefore, the solution provided by the Budapest Treaty is to permit an IDA to furnish a sample of a particular microorganism only if the request is accompanied by the written authorization of the depositor or by a certificate from a competent industrial property office indicating the legitimacy of the request, or, alternatively, if a competent industrial property office has already notified the IDA that the microorganism may be distributed without the need for such authorization. These matters are governed by Rule 11, which recognizes three different situations in which samples may be furnished, viz. to interested industrial property offices (Rule 11.1), to or with the authorization of the depositor (Rule 11.2), or to parties legally entitled (Rule 11.3).

(b) Requests from Interested Industrial Property Offices

89. When the industrial property office of a Contracting State or an intergovernmental industrial property organization requests a sample of a deposited microorganism, Rule 11.1 states that the request must be accompanied by a declaration to the effect that:

- “(i) an application referring to the deposit of that microorganism has been filed with that office for the grant of a patent and that the subject matter of that application involves the said microorganism or the use thereof;
- (ii) such application is pending before that office or has led to the grant of a patent;
- (iii) the sample is needed for the purposes of a patent procedure having effect in the said Contracting State or in the said organization or its member States;
- (iv) the said sample and any information accompanying or resulting from it will be used only for the purposes of the said patent procedure.”

This Rule clearly indicates that an “interested” industrial property office is one that either is processing a patent application or has granted a patent in respect of the deposited microorganism. The above provisions also prohibit such an office from using a sample of the microorganism (or information about it) for any purposes other than its own procedures.

(c) Requests from or with the Authorization of the Depositor

90. Rule 11.2 states:

“Any international depositary authority shall furnish a sample of any deposited microorganism:

- (i) to the depositor, on his request;
- (ii) to any authority, natural person or legal entity (hereinafter referred to as ‘the authorized party’), on the request of such party, provided that the request is accompanied by a declaration of the depositor authorizing the requested furnishing of a sample.”

These provisions recognize the right of the depositor both to obtain a sample of his own deposited microorganism whenever he wishes and to permit the furnishing of a sample to whomever he pleases, regardless of whether that person is otherwise “legally entitled.” However, the depositor does not have the right to prevent the furnishing of samples to parties legally entitled, whatever his personal wishes may be.

(d) Requests from Parties Legally Entitled

(i) Requests Requiring Industrial Property Office Certification

91. The furnishing of samples in the vast majority of cases is governed by Rule 11.3, which provides two alternative mechanisms. The first of these is given by Rule 11.3(a), which states:

“(a) Any international depositary authority shall furnish a sample of any deposited microorganism to any authority, natural person or legal entity (hereinafter referred to as ‘the certified party’), on the request of such party, provided that the request is made on a form whose contents are fixed by the Assembly and that on the said form the industrial property office certifies:

(i) that an application referring to the deposit of that microorganism has been filed with that office for the grant of a patent and that the subject matter of that application involves the said microorganism or the use thereof;

(ii) that, except where the second phrase of (iii) applies, publication for the purposes of patent procedure has been effected by that office;

(iii) either that the certified party has a right to a sample of the microorganism under the law governing patent procedure before that office and, where the said law makes the said right dependent on the fulfillment of certain conditions, that that office is satisfied that such conditions have actually been fulfilled or that the certified party has affixed his signature on a form before that office and that, as a consequence of the signature of the said form, the conditions for furnishing a sample to the certified party are deemed to be fulfilled in accordance with the law governing patent procedure before that office; where the certified party has the said right under the said law prior to publication for the purposes of patent procedure by the said office and such publication has not yet been effected, the certification shall expressly state so and shall indicate, by citing it in the customary manner, the applicable provision of the said law, including any court decision.”

These provisions are intended to protect both the depositor and the IDA from the danger of samples being furnished illegally or mistakenly. They ensure that not only must the requesting party obtain certification of entitlement from the industrial property office, but also that the industrial property office must effectively state that it is competent to provide such certification, i.e., that it is actually processing an application referring to the microorganism (either in its capacity as a national office or, in the case of an international application filed under the Patent Cooperation Treaty (PCT), as a “designated Office” within the meaning of that Treaty (Rule 11.5)), and that the requesting party meets all the conditions required by the applicable law. Moreover, where the requesting party is entitled to receive a sample before publication of the patent application, the industrial property office must refer to the actual provision of the law which grants such entitlement. Except where Rules 11.1, 11.2 or 11.3(b) apply, any request not made out on the appropriate form or endorsed as above by the industrial property office will automatically be refused by an IDA. In the case of an international application filed under the PCT, the certification of publication required by Rule 11.3(a)(ii) can, at the option of the industrial property office, certify either international publication under the PCT or publication by that office in its own right (Rule 11.5). It should also be noted that some industrial property offices (see Section E of this Guide) may require a form additional to that just mentioned to be completed by the requesting party and may have to provide additional certification to comply with their own national law.

(ii) Requests not Requiring Industrial Property Office Certification

92. The alternative mechanism for the furnishing of samples to parties legally entitled is given by Rule 11.3(b), which states:

“(b) In respect of patents granted and published by any industrial property office, such office may from time to time communicate to any international depositary authority lists of the accession numbers given by that authority to the deposits of the microorganisms referred to in the said patents. The international depositary authority shall, on the request of any authority, natural person or legal entity (hereinafter referred to as ‘the requesting party’), furnish to it a sample of any microorganism where the accession number has been so communicated. In respect of deposited microorganisms whose accession numbers have been so communicated, the said office shall not be required to provide the certification referred to in Rule 11.3(a).”

By notifying the IDA of the accession numbers of microorganisms cited in published patents, industrial property offices in countries whose laws require that such organisms must be available without restrictions to anyone once the relevant patents have been granted and published are able to circumvent the certification procedures of Rule 11.3(a). In practice, however, such notification is provided by very few industrial property offices and IDAs are often left to ascertain for themselves whether the relevant patents have been issued.

(e) Common Procedures

93. Procedures that must be followed in respect of all requests for the furnishing of samples are laid down in Rule 11.4(a) to (e). Rule 11.4(a) and (b) deals with the languages in which any request, declaration, certification or other communication referred to in Rules 11.1, 11.2 and 11.3 must be written. Such communications must be in English, French, Russian or Spanish where they are addressed to an IDA whose official language is or whose official languages include English, French, Russian and Spanish, respectively. However, where the official language of the IDA is Russian or Spanish, any communication addressed to it may still be in English or French, in which case the International Bureau of WIPO will provide, on request and free of charge, a certified translation into Russian or Spanish. Conversely, where a request for a sample is made by an industrial property office (Rule 11.1) whose official language is Russian or Spanish, the request may be made in Russian or Spanish regardless of the official language of the IDA. In this case, the International Bureau will provide, on request and free of charge, a certified translation into English or French.

94. Rule 11.4(c) requires any request, etc., made under Rules 11.1, 11.2 or 11.3 to be in writing and to be signed and dated. Rule 11.4(d) states that any request, etc., made under Rules 11.1, 11.2 or 11.3(a) (not 11.3(b)) must contain:

“(i) the name and address of the industrial property office making the request, of the authorized party or of the certified party, as the case may be;

(ii) the accession number given to the deposit;

(iii) in the case of Rule 11.1, the date and number of the application or patent referring to the deposit;

(iv) in the case of Rule 11.3(a), the indications referred to in (iii) and the name and address of the industrial property office which has made the certification referred to in the said Rule.”

In the case of any request made under Rule 11.3(b), only the name and address of the requesting party and the accession number of the deposit need be given (Rule 11.4(e)). However, as already mentioned (paragraph 92), Rule 11.3(b) is rarely invoked and in practice delays can be avoided if the request is also accompanied by evidence of the issuance of a patent referring to the particular microorganism.

(f) Procedures for Furnishing Samples

(i) Indications Provided by the IDA

95. Rule 11.4(f) to (h) deals with the procedures to be followed by the IDA when actually furnishing samples. Rule 11.4(f) states:

“The container in which the sample furnished is placed shall be marked by the international depositary authority with the accession number given to the deposit and shall be accompanied by a copy of the receipt referred to in Rule 7, an indication of any properties of the microorganism which are or may be dangerous to health or the environment and, upon request, an indication of the conditions which the international depositary authority employs for the cultivation and storage of the microorganism.”

Except for the requirement to supply a copy of the receipt, these are obvious provisions which most culture collections apply in any case when sending out cultures of microorganisms.

(ii) Notification of the Depositor

96. Rule 11.4(g) states:

“The international depositary authority having furnished a sample to any interested party other than the depositor shall promptly notify the depositor in writing of that fact, as well as of the date on which the said sample was furnished and of the name and address of the industrial property office, of the authorized party, of the certified party or of the requesting party, to whom or to which the sample was furnished. The said notification shall be accompanied by a copy of the pertinent request, of any declarations submitted under Rules 11.1 or 11.2(ii) in connection with the said request, and of any forms or requests bearing the signature of the requesting party in accordance with Rule 11.3.”

This Rule recognizes the right of the depositor to be informed in every case when, to whom and under what conditions samples of his microorganism have been furnished. In practice, however, some depositors indicate in writing to the IDA that they wish to waive their right to be so informed. In such cases, most IDAs will comply with the depositor’s wish; in fact,

some charge a lower fee for storage if the depositor waives this right (see Section D of this Guide).

(iii) Fees

97. A fee may be charged by the IDA for the furnishing of samples (Rule 12.1(a)(iv)) in all cases except where the recipient is an industrial property office, in which case the sample must be supplied free of charge (Rule 11.4(h)).

98. Any party entitled under Rules 11.1, 11.2 or 11.3 to receive a sample of a deposited microorganism is also entitled to be supplied, on request, with a copy of the most recent scientific description and/or proposed taxonomic designation relating to the microorganism (Rule 7.6), provided, of course, that the IDA has previously received such information from the depositor under Rules 6.1(b), 6.2(a)(iii) or 8.1(b)(iii) (see Section A of this Guide). The IDA is permitted to charge a fee for the communication of the description/designation in such cases (Rule 12.1(a)(v)). This fee, like all fees charged by the IDA, cannot be varied according to the nationality or residence of the party paying it (Rule 12.1(c)).

(g) Guidelines to Making a Valid Request for a Sample

(i) General

99. Subsections (a) to (f) have detailed and explained the requirements that must be met to effect the furnishing of a sample of a microorganism deposited under the Budapest Treaty. The purpose of this subsection is to translate these requirements into the practical steps that a third party (other than an industrial property office) should take in order to obtain a sample of such a microorganism.

100. Except where Rule 11.3(b) applies, anyone making a simple request for a sample of a particular microorganism, without any authorization or certification, can expect the IDA to ask him to do one of the following:

- obtain the authorization of the depositor (Rule 11.2(ii); see paragraph 101);
- obtain certification from the appropriate industrial property office, in which case the IDA may or may not supply him with the relevant forms (Rule 11.3(a); see paragraphs 102 and 103);
- provide evidence of the issuance of a US patent. (This is necessary because samples must be available without restriction when a US patent has issued, but the industrial property office does not invoke Rule 11.3(b); see paragraph 104.)

(ii) Obtaining Samples with the Authorization of the Depositor

101. The procedure which the requesting party should follow to obtain a sample with the authorization of the depositor is self-evident. He should approach the depositor, ask him for a written, dated, signed declaration authorizing the IDA to furnish to him a sample of the microorganism in question (if he wishes, he can use form BP/11 for this, which can be

obtained from the IDA, although it is not essential). He should then send this declaration along with his request (and a purchase order) to the IDA. However, Rule 11.2(ii) presupposes that the requesting party knows who the depositor is. If he does not, he cannot expect the IDA to divulge this information to him (Rule 9.2; see paragraph 41). Thus there is little point in anyone who does not already know the identity of the depositor attempting to obtain a sample by this route.

(iii) Obtaining Samples with Industrial Property Office Certification

102. A request for a sample with industrial property office certification must be made on a form corresponding to form BP/12 (see Appendix 3), which ensures that the indications required by Rules 11.3(a) and 11.4(d) are given. Commonly, form BP/12 itself is used, although certain offices may have their own version of it. For example, the European Patent Office uses a form which combines the requirements of Rules 11.3(a) and 11.4(d) of the Budapest Treaty with those of Rule 28 of the European Patent Convention. Also, some offices may require additional forms to be completed in respect of their own national procedures. The equivalent of form BP/12, and any other appropriate forms, obviously can be obtained from the relevant industrial property office(s). Also many IDAs (see Section D of this Guide) keep stocks of them and will supply copies on request. Rule 11.3(a) assumes, however, that the requesting party knows which industrial property offices are competent to provide certification (i.e., where applications have been filed) in respect of the particular microorganism being asked for. If he does not, he should not assume that because the IDA can provide him with form BP/12, it can also tell him where to send it. In many cases, IDAs do not know where applications have been filed in respect of microorganisms deposited with them.

103. To obtain a sample of a microorganism under Rule 11.3(a), the requesting party should:

- (a) ask the competent industrial property office, or the IDA, for a copy of the form to be used for requesting samples of microorganisms according to Rule 11.3(a) of the Budapest Treaty;
- (b) complete that part of the form to be filled in by “the requesting party;”
- (c) send the entire form to the industrial property office, not to the IDA, along with any fee that may be payable;
- (d) when the form bearing the appropriate certification is received back from the industrial property office, send it to the IDA along with a normal purchase order.

(iv) Obtaining Samples of Deposits Cited in US Patents

104. In the United States of America, patent applications are not published before the patent is granted, and after grant any microorganism referred to in the published patent must be available to the public without restriction. Because of this, the certification procedures of Rule 11.3(a) are not relevant to US practice. Rule 11.3(b) of the Treaty, whereby lists of microorganisms mentioned in published patents are communicated to the IDA, is intended to deal with this situation. However, as already mentioned, Rule 11.3(b) is not invoked by the US industrial property office. Thus the IDA may not know that a particular microorganism is

the subject of a US patent and hence freely available. Anyone requesting a microorganism which is referred to in a published US patent, therefore, should ascertain whether the IDA is aware of such publication. If it is not, he should accompany his request with the number and date of the patent, the name(s) of the applicant(s) and a copy of the page referring to the accession number of the microorganism as evidence of publication. If the requesting party is not able to supply such evidence, he must expect the furnishing of a sample to be delayed until the IDA has verified that publication has occurred. If the IDA is already aware of such publication, however, it is likely to furnish the sample in accordance with Rule 11.3(b).

(v) Obtaining Samples under Rule 11.3(b)

105. To obtain a sample pursuant to Rule 11.3(b), a requesting party merely needs to give his name and address and quote the accession number of the microorganism.

(vi) Health and Safety Requirements

106. It should be noted that the procedures described in this subsection relate only to the right to receive samples of microorganisms according to patent law. They do not override any requirements to be met in respect of import and quarantine regulations, health and safety procedures, plant disease regulations, etc. Thus as well as obtaining any certification required by the Budapest Treaty, anyone requesting a sample must ensure that he has obtained any permit or license and complies with any safety requirements necessary for handling the organism in question.

PART II: SPECIFIC REQUIREMENTS OF INDIVIDUAL INTERNATIONAL
DEPOSITARY AUTHORITIES AND INDUSTRIAL PROPERTY OFFICES

Section D: Requirements of
International Depositary Authorities (IDAs)

(a) Culture Collections Currently Holding IDA Status

The following 31 depositary institutions in 19 countries have acquired the status of IDA:

AU Australia

Australian Government Analytical Laboratories (AGAL)

BE Belgium

Belgian Coordinated Collections of Microorganisms (BCCMTM)

BG Bulgaria

National Bank for Industrial Microorganisms and Cell Cultures (NBIMCC)

CA Canada

Bureau of Microbiology at Health Canada (BMHC)

CN China

China Center for Type Culture Collection (CCTCC)

China General Microbiological Culture Collection Center (CGMCC)

CZ Czech Republic

Czech Collection of Microorganisms (CCM)

DE Germany

Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH
(DSMZ)

ES Spain

Colección Española de Cultivos Tipo (CECT)

FR	France Collection nationale de cultures de micro-organismes (CNCM)
GB	United Kingdom Culture Collection of Algae and Protozoa (CCAP) European Collection of Cell Cultures (ECACC) International Mycological Institute (IMI) National Collection of Type Cultures (NCTC) National Collection of Yeast Cultures (NCYC) National Collections of Industrial, Food and Marine Bacteria (NCIMB)
HU	Hungary National Collection of Agricultural and Industrial Microorganisms (NCAIM)
IT	Italy Advanced Biotechnology Center (ABC) Collection of Industrial Yeasts DBVPG
JP	Japan National Institute of Bioscience and Human-Technology (NIBH)
KR	Republic of Korea Korean Cell Line Research Foundation (KCLRF) Korean Collection for Type Cultures (KCTC) Korean Culture Center of Microorganisms (KCCM)
LV	Latvia Microbial Collection of Latvia (MSCL)
NL	Netherlands Centraalbureau voor Schimmelcultures (CBS)

RU Russian Federation

National Research Center of Antibiotics (NRCA)

Russian Collection of Microorganisms (VKM)

Russian National Collection of Industrial Microorganisms (VKPM),
GNII Genetika

SK Slovakia

Culture Collection of Yeasts (CCY)

US United States of America

Agricultural Research Service Culture Collection (NRRL)

American Type Culture Collection (ATCC)

(b) List of Kinds of Microorganisms Accepted by IDAs

	ABC (IT)	AGAL (AU)	ATCC (US)	BCCM™ (BE)	BMHC (CA)	CBS (NL)	CCAP (GB)	CCM (CZ)	CCTCC (CN)	CCY (SK)	CECT (ES)
Algae			X				X		X		
Animal viruses			X						X		
Animal cell cultures	X		X	X	X				X		
Bacteria (pathogenic)			X	X	X	X		X	X		X
Bacteria (non-pathogenic)		X	X	X	X	X		X	X		X
Bacteriophages			X		X	X			X		
Embryos			X								
Eukaryotic DNA			X								
Fungi (pathogenic)			X	X	X	X		X	X		
Fungi (non-pathogenic)		X	X	X	X	X		X	X		X
Human cell cultures	X		X	X		X			X		
Hybridomas	X		X	X	X	X			X		
Molds			X								
Murine embryos			X								
Mycoplasma			X								
Oncogenes			X	X							
Plant cell cultures			X						X		
Plant viruses			X						X		
Plasmids (in hosts)			X	X		X		X	X		
Plasmids (not in hosts)			X	X		X			X		
Protozoa (parasitic)			X		X						
Protozoa (non-parasitic)			X		X		X				
Protozoa (pathogenic)			X		X						
RNA			X	X							
Seeds			X						X		
Yeasts (pathogenic)			X	X	X	X		X	X	X	
Yeasts (non-pathogenic)		X	X	X	X	X		X	X	X	X

(b) List of Kinds of Microorganisms Accepted by IDAs

	CGMCC (CN)	CNCM (FR)	DBVPG (IT)	DSMZ (DE)	ECACC (GB)	IMI (GB)	KCCM (KR)	KCLRF (KR)	KCTC (KR)	MSCL (LV)	NBIMCC (BG)
Algae	X								X		
Animal viruses	X	X			X		X		X		X
Animal cell cultures		X		X	X			X	X		X
Bacteria (pathogenic)	X	X			X					X	
Bacteria (non-pathogenic)	X	X		X	X	X	X		X	X	X
Bacteriophages	X	X		X			X		X		
Embryos									X		
Eukaryotic DNA					X				X		
Fungi (pathogenic)	X	X			X					X	
Fungi (non-pathogenic)	X	X	X	X		X	X		X	X	X
Human cell cultures		X		X	X						
Hybridomas		X			X		X	X	X		X
Molds											
Murine embryos				X							
Mycoplasma	X										
Oncogenes											
Plant cell cultures				X	X			X			
Plant viruses	X			X			X		X		X
Plasmids (in hosts)	X	X		X			X		X	X	X
Plasmids (not in hosts)	X			X			X				
Protozoa (parasitic)					X						
Protozoa (non-parasitic)									X		
Protozoa (pathogenic)					X						
RNA											
Seeds											
Yeasts (pathogenic)	X	X			X					X	
Yeasts (non-pathogenic)	X	X	X	X		X	X		X	X	X

(b) List of Kinds of Microorganisms Accepted by IDAs

	NCAIM (HU)	NCIMB (GB)	NCTC (GB)	NCYC (GB)	NIBH (JP)	NRCA (RU)	NRRL (US)	VKM (RU)	VKPM (RU)
Algae					X				
Animal viruses									
Animal cell cultures					X				X
Bacteria (pathogenic)		X	X						
Bacteria (non-pathogenic)	X	X			X	X	X	X	X
Bacteriophages		X							X
Embryos					X				
Eukaryotic DNA									X
Fungi (pathogenic)									
Fungi (non-pathogenic)	X				X	X	X	X	X
Human cell cultures									X
Hybridomas									X
Molds	X						X		
Murine embryos									
Mycoplasma									
Oncogenes									
Plant cell cultures					X				X
Plant viruses									
Plasmids (in hosts)		X	X	X	X	X	X	X	X
Plasmids (not in hosts)		X			X				
Protozoa (parasitic)									
Protozoa (non-parasitic)					X				
Protozoa (pathogenic)									
RNA									
Seeds		X			X				
Yeasts (pathogenic)									
Yeasts (non-pathogenic)	X	X		X	X	X	X	X	X

(c) Detailed Requirements and Practices of IDAs

(i) General

This subsection describes in detail the requirements and practices of each IDA as they relate to the deposit of microorganisms and the furnishing of samples under the Budapest Treaty. Information is based on communications and notifications published from time to time in WIPO's monthly review *Industrial Property*, as of January 1, 1995, in *Industrial Property and Copyright*, and as of June 1998, in *Intellectual Property Laws and Treaties*, and on the replies to a questionnaire sent to all IDAs by the Director General of WIPO. The IDAs are listed alphabetically by country and the information on each is arranged in the format given in (ii), below. Reference to "model forms" and "international forms" means those forms designed by the International Bureau of WIPO, published in WIPO document BP/A/II/12 (1981), and which are reproduced in Appendix 3.

(ii) Information on IDAs

For each IDA, information is arranged as follows:

country, name of international depositary authority and acronym, address, telephone, telex and telefax numbers, if any, references to publication in *Industrial Property*, as of January 1, 1995, in *Industrial Property and Copyright*, and, as of June 1998, in *Intellectual Property Laws and treaties*.

IDAs are listed according to the two-letter country code in accordance with WIPO Standard ST.3.

1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

The different types of biological entities accepted for deposit and any specific exclusions are given. The maximum hazard rating and/or physical containment requirements acceptable to the IDA in respect of microorganisms that may be deposited are stated.

(b) Technical Requirements and Procedures

(i) Form and Quantity

The state in which cultures must be submitted is given, e.g., lyophilized, frozen, liquid suspension, agar slant, etc. The minimum number of replicates that must be supplied by the depositor and the minimum titre of each culture (where appropriate) are stated.

(ii) Time Required for Viability Testing

The average and maximum length of time (in days) needed by the IDA to carry out viability tests is given for each kind of microorganism accepted.

(iii) Depositor Checks and Renewal of Stocks

Information is given whether the IDA subcultures material supplied by the depositor to provide stocks of samples for storage; whether it stores samples originally supplied by the depositor; how it replenishes diminishing stocks; and whether it requires the depositor to test for authenticity samples of its own preparations.

(c) Administrative Requirements and Procedures

(i) General

Language. The official language(s) and any other language(s) in which the IDA accepts communications are given.

Contract. Information is given about the kind of contract (if any) that the IDA enters into with the depositor.

Import and/or Quarantine Regulations. Information is given whether any of the microorganisms accepted by the IDA are subject to import and/or quarantine regulations; the requirements for compliance with such regulations; and the government departments where further advice may be obtained.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. Reference is made to any forms that must be completed; any information that must be given to the IDA in advance of deposit; and any special transport and/or delivery arrangements.

Official Notifications to the Depositor. Reference is made to any forms that the IDA uses to issue official notifications to the depositor.

Unofficial Notifications to the Depositor. An indication is given whether the IDA will telephone or telex information to the depositor in advance of any official notifications.

Supply of Information to a Patent Agent. An indication is given whether the IDA will supply copies of documents to the depositor's patent agent.

(iii) Converting a Previous Deposit

Information is given about the requirements of the IDA that the depositor must meet and the extent to which he is permitted to convert a deposit previously made outside the Budapest Treaty to one made under the Treaty.

(iv) Making a New Deposit

Any requirements of the IDA additional to those that must be met when making an original deposit are indicated.

2. Furnishing of Samples

(a) Requests for Samples

Information is given whether the IDA advises third parties of the correct procedures to follow in order to make a valid request; whether the IDA supplies the requesting party with the appropriate forms; whether the requesting party must meet any health and safety requirements; whether samples furnished by the IDA are from its own preparations or from those supplied by the depositor.

(b) Notification of the Depositor

The means whereby the IDA notifies the depositor of the furnishing of samples is given.

(c) Cataloguing of Budapest Treaty Deposits

It is stated whether, and under what conditions, the IDA lists deposits under the Budapest Treaty in its published catalogs.

3. Schedule of Fees

The fees payable to the IDA for procedures carried out under the Budapest Treaty are listed.

4. Guidance for Depositors

Reference is made to any publications that the IDA makes available for the guidance of prospective depositors.

AU – AUSTRALIA

AUSTRALIAN GOVERNMENT ANALYTICAL LABORATORIES (AGAL)

The New South Wales Regional Laboratory
1, Suakin Street
PYMBLE, N.S.W. 2073
Australia

Telephone: (02) 449 0111
Telex: (02) AA61906 AUSCI
Telefax: (02) 449 1653
Internet home page: <http://www.eidn.com.au/actwaterindustryagal.htm>

(See *Industrial Property*, 1988, p. 329; 1990, p. 99.)

1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

Bacteria (including actinomycetes), yeasts and fungi, other than known human and animal pathogens, with a hazard categorization no greater than WHO Classification Risk Group 2 (“Laboratory Acquired Infections,” C.H. Collins, Butterworths, 1983), that can be preserved without significant change to their properties by the methods of preservation in use (freezing and freeze-drying).

Nucleic acid preparations and phages may be accepted if the depositor certifies that they pose no hazard when handled by normal laboratory procedures and the depositor supplies suitable material for preservation. At this stage, AGAL cannot undertake to culture such preparations and the depositor is requested to carry out checks of authenticity.

At present, AGAL does not accept for deposit animal, plant, algal and protozoal cultures, cultures of viral, rickettsial and chlamydial agents, microorganisms which may require in the view of the curator special attention to handling and preparation for storage.

(b) Technical Requirements and Procedures

(i) Form and Quantity

Microorganisms must be submitted for deposit as lyophilized preparations or on culture media. The minimum number of replicates that must be provided by the depositor when making his deposit and the form in which they must be submitted are as follows:

bacteria, fungi and yeasts	6 lyophilized or on culture media
phages and plasmids	sufficient quantity and titre for preservation

(ii) Time Required for Viability Testing

The average length of time required for testing the viability of the various kinds of microorganisms accepted by AGAL is given below:

bacteria	5 days
fungi	10 days
yeasts	10 days

(iii) Depositor Checks and Renewal of Stocks

AGAL prepares its own batches of bacteria, fungi and yeasts by subculturing material supplied by the depositor. New batches are prepared by asking the depositor to make a new deposit under Article 4, by subculturing AGAL's own preparation with the approval of the depositor, or by subculturing material originally supplied by the depositor. The depositor is asked to check the authenticity of batches prepared by AGAL from material supplied by him at the time of deposit and thereafter. AGAL stores original material supplied by the depositor.

(c) Administrative Requirements and Procedure

(i) General

Language. The official language of AGAL is English.

Contract. At present, AGAL does not enter into a written contract with the depositor defining the liabilities of either party.

Import and/or Quarantine Regulations. Certain kinds of microorganisms accepted for deposit by AGAL are subject to import and quarantine regulations. AGAL will arrange the necessary permits for importation of biological materials and clearing any quarantine requirements. The depositor must contact AGAL before depositing any microorganisms. The time required to obtain the permit may vary depending on the kinds of microorganisms to be deposited. Further information may be obtained from the Australian Quarantine Inspection Service, GPO Box 858, Canberra, A.C.T., 2601 Australia.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. The depositor is requested to complete model form BP/1. In the event of a later indication or amendment of the scientific description and/or proposed taxonomic designation, the depositor must complete model form BP/7.

Official Notifications to the Depositor. The receipt and viability statement are issued, respectively, on mandatory "international forms" BP/4 and BP/9. Attestation of receipt of a later indication or amendment of the scientific description and/or proposed taxonomic designation is issued on model form BP/8. Notification to the depositor that a sample of the deposited microorganism has been furnished to an entitled party is issued on model form BP/14. Standard forms are not used for other notifications.

Unofficial Notifications to the Depositor. If requested, AGAL will telephone or telex the date of deposit and accession number after the microorganism has been received, but before the official receipt is issued. Similarly, AGAL will communicate the result of the viability test before the viability statement is issued.

Supply of Information to a Patent Agent. AGAL asks the depositor at the time of deposit to supply the name and address of his patent agent and, if requested, it will send copies of the receipt and the viability statement to both the depositor and his patent agent.

(iii) Converting a Previous Deposit

Deposits made outside the provisions of the Budapest Treaty may be converted to deposits under the Budapest Treaty, whether or not they were originally deposited for patent purposes. In addition to the administrative requirements for conversion, which are the same as those to be met in respect of an original deposit under the Budapest Treaty, AGAL requests the depositor to verify the authenticity of his deposited material at the time of conversion.

(iv) Making a New Deposit

When making a new deposit, the depositor is required to complete model form BP/2 and to supply copies of the documents specified under Rule 6.2; otherwise, the procedure is similar to that when making an original deposit.

2. Furnishing of Samples

(a) Requests for Samples

AGAL advises requesting parties of the correct procedure to follow to make a valid request. In the case of requests requiring proof of entitlement, AGAL will provide requesting parties with copies of model request form BP/12 and/or requests forms used by individual industrial property offices. It will also advise requesting parties on the requirements provided for under the Australian Patent Act.

AGAL furnishes a sample of a dangerous microorganism only after having received confirmation that the requesting party is capable of handling the microorganism safely.

(b) Notification of the Depositor

Depositors are notified when samples of their microorganism have been furnished to third parties.

(c) Cataloguing of Budapest Treaty Deposits

At present, AGAL does not publish a catalog.

3. Schedule of Fees

	Australian dollars
(a) Storage	750
(b) Issuance of viability statement	90
(c) Furnishing of samples	60

4. Guidance for Depositors

Guidance notes for prospective depositors are in preparation.

BE – BELGIUM

BELGIAN COORDINATED COLLECTIONS OF MICROORGANISMS (BCCM™)

Headquarters:

Prime Minister's Services
Federal Office for Scientific, Technical and Cultural Affairs (OSTC)
8, rue de la Science
1000 BRUSSELS
Belgium

Telephone: (322) 2383411
Telefax: (322) 2305912
Internet home page: <http://www.belspo.be/bccm/>

Collections:

Institut scientifique de la Santé publique - Louis Pasteur (BCCM™/IHEM)
Section mycologie
14, rue J. Wytsman
1050 BRUSSELS
Belgium

Telephone: (322) 6425630
Telefax: (322) 6425519

Vakgroep voor Moleculaire Biologie-Plasmidencollectie (BCCM™/LMBP)
Universiteit Gent
K.L. Ledeganckstraat 35
9000 GHENT
Belgium

Telephone: (329) 2645347
Telefax: (329) 2645348

Note: Depositors are requested to deal with all applications and deposits directly with the BCCM™ Collection concerned (see item 1(a) below). The required forms may also be obtained from the BCCM™ Collection approached.

Laboratorium voor Microbiologie-Bacteriënverzameling (BCCMTM/LMG)

Universiteit Gent

K.L. Ledeganckstraat 35

9000 GHENT

Belgium

Telephone: (329) 2645108

Telefax: (329) 2645346

Mycothèque de l'Université Catholique de Louvain (BCCMTM/MUCL)

Place Croix du Sud 3

1348 LOUVAIN-LA-NEUVE

Belgium

Telephone: (3210) 473742

Telefax: (3210) 451501

(See *Industrial Property*, 1992, p. 49; 1993, p. 214; *Industrial Property Laws and Treaties*, 1998, p. 45.)

1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

BCCMTM accept for deposit:

BCCMTM/IHEM Collection: filamentous fungi and yeasts, including pathogenic fungi and yeasts that cause mycosis in man and animals, and actinomycetes;

BCCMTM/LMBP Collection:

— genetic material, whether recombinant or not—plasmids, oncogenes and RNA, for example—in the form of an isolated material preparation or in a host;

— animal cell cultures, including human cell lines, genetically modified cell lines and hybridomas. Cell cultures contaminated by mycoplasmas can only be accepted for deposit in exceptional cases.

In the case of the two above-mentioned categories, LMBP does not normally accept any deposit requiring a containment level beyond category 3 of the United Kingdom Advisory Committee on Genetic Manipulation (ACGM);

BCCM™/LMG Collection: all bacterial strains, including actinomycetes, but excepting pathogens belonging to a hazard group higher than Group 2 of the UK Advisory Committee on Dangerous Pathogens¹;

BCCM™/MUCL Collection: filamentous fungi and yeasts, including phytopathogens, but excepting pathogenic fungi causing mycosis in man and animals belonging to a hazard group higher than Group 2 of the UK Advisory Committee on Dangerous Pathogens.²

As a general rule, the BCCM™ Collections will accept only strains that can be cultured under conditions technically feasible for the collection concerned and conserved, other than in continuous vegetative activity, without inducing significant changes in their characteristics.

Exceptionally, the BCCM™ Collections may accept deposits that cannot be conserved other than by active culture, but acceptance of such a deposit will have to be decided on a case-by-case basis after prior negotiation with the potential depositor. They may also exceptionally accept, following the same case-by-case negotiation procedure, the deposit of mixtures of microorganisms, whereby non-defined or non-identifiable mixtures will be automatically excluded.

The BCCM™ Collections also reserve their right to refuse the deposit of biological material which, according to the curator, represents an unacceptable hazard or which is not suitable, for technical reasons, for manipulation.

(b) Technical Requirements and Procedures

(i) Form and Quantity

- Bacteria, filamentous fungi, yeasts, actinomycetes or genetic material in a host:

The depositor must supply:

3 active or freeze-dried or cryogenically conserved cultures of the same batch, one of which will be subjected to a viability test and subsequently serve to prepare a minimum stock of 20 samples of cryogenically conserved cells and/or 20 ampoules of freeze-dried cells³;

or

23 ampoules of freeze-dried cells of the same preparation, one of which will be subjected to a viability test and subsequently serve for the preparation of a minimum stock of 20 cryogenically conserved samples.

- Genetic material in the form of a preparation of isolated material:

¹ “Categorisation of Pathogens according to Hazard and Categories of Containment,” HMSO, London, ISBN 011 88761-3.

² Ditto.

³ These freeze-dried cultures will be prepared by BCCM™ for a fee comparable to the usual price of freeze-drying a batch of 20 ampoules of a single strain.

Samples must be supplied in freeze-dried or cryogenically conserved form or precipitated in alcohol. A minimum of 2 x 20 micrograms must be furnished.

Plasmids must have a degree of purity such that ready transformation is ensured (the recommended host must normally be stated and furnished--without the plasmid concerned--together with sufficiently detailed instructions for ensuring ready transformation).

– Human and animal cells, hybridomas:

Before dispatching the animal and human cell cultures or the hybridomas, the depositor must check for contaminants. The cells must be submitted for deposit in the form of frozen cultures. BCCMTM/LMBP may refuse to accept the deposit of cultures not packed in a sufficient quantity of dry ice to ensure that they remain frozen during transport. On deposit, the depositor must submit at least 12 samples of the same preparation in well-closed tubes of the cryotube type (12 to 13 mm diameter; volume: 1-2 milliliters), clearly and durably marked. The cultures must contain at least 4 x 10⁶ viable cells/ampoule. One or two samples will be tested for viability.

(ii) Time required for Viability Testing

The minimum periods required by BCCMTM to test the viability of various types of microorganisms are as follows (however, depositors should be aware that the viability test may take longer for certain types of microorganism):

bacteria	2 days
filamentous fungi	3 days
yeasts	2 days
genetic material ¹	2 days
human and animal cell cultures, hybridomas	3 weeks ²

(iii) Depositor Checks and Renewal of Stocks

At the time of deposit, BCCMTM prepare, depending on the form in which the microorganisms have been supplied, their own freeze-dried, cryogenically preserved or deep-frozen batches as described in item (i) above. Subsequently, to renew their depleted stocks, BCCMTM prepare, as needed, new batches on the basis of those subcultures. The depositor is required to check the authenticity of samples of all the batches of his microorganism prepared by BCCMTM and to inform them of the result of his checking. In general, BCCMTM do not prepare their own batches of genetic material, animal and human cell lines or hybridomas. Consequently, when stocks of material are exhausted following furnishing of samples, they request the depositor to make a new deposit. Whatever the method used to prepare the sample

¹ For genetic material in the form of a preparation of isolated material, the “viability test” includes transformation of the suitable host. If the host is transformed, the “viability test” is deemed positive.

² The “viability test” includes testing for mycoplasma contamination

batches for distribution and where the supplied culture so permits, BCCMTM conserve a part of the original material.

(c) Administrative Requirements and Procedures

(i) General

Language. The official language of BCCMTM is English. Communications are also accepted in German, French and Dutch.

Contract. The application form BCCMTM/acron/DBT1,¹ which must be completed by the depositor, constitutes a contract under which the depositor is required:

- to communicate all information requested by BCCMTM;
- to pay all required fees;
- not to withdraw his deposit during the required conservation period;
- to authorize BCCMTM to furnish samples in accordance with the requirements applicable to patents;
- to make a new deposit in the event of BCCMTM not being in a position to supply samples;
- not to make BCCMTM liable for any deterioration of samples during conservation if all the precautions he has described for that conservation have been taken by BCCMTM;
- to compensate BCCMTM for any prejudice they may incur as a result of the handling of the microorganism for which they are responsible if all the precautions he has described with respect to such handling have been taken by BCCMTM;
- to compensate BCCMTM for any court action that may be taken against them following the supply of samples, unless such action is based on negligence on the part of BCCMTM.

Once the deposit and acceptance procedure has been completed, the depositor receives a form BCCMTM/acron/DBT2 to remind him that he is bound by the contract thus concluded. Belgian law applies to any dispute.

Import and/or Quarantine Regulations. Certain types of microorganisms accepted by BCCMTM are subject to import or quarantine regulations. Where that is the case, the depositor

¹ All the forms used by BCCMTM bear a reference number of the type BCCMTM/acron/num; “acron” is replaced by the acronym (IHEM, LMBP, LMG, MUCL) of the Collection concerned; “num” is replaced by the individual number of the form. Numbering of the type “BP/..” indicates that it is a compulsory international form or some other standard form.

must communicate the name of the species of the microorganism to BCCMTM to enable the necessary measures to be taken.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. The depositor is required to complete, in addition to the application form BCCMTM/acron/DBT1 (see (i) above), a form BCCMTM/acron/BP/1, which is the deposit form required by the Budapest Treaty. In the event of a subsequent communication or modification of the scientific description or the proposed taxonomic designation and also for any request for attestation that BCCMTM have received such information, the depositor should preferably complete the form BCCMTM/acron/BP/7.

Official Notifications to the Depositor. The receipt and the viability statement are issued on the compulsory “international forms,” BCCMTM/acron/BP/4 and BCCMTM/acron/BP/9, respectively. The attestation of receipt of communication or subsequent amendment of the scientific description and/or the proposed taxonomic designation is issued on the form BCCMTM/acron/BP/8. The notification on the furnishing of samples to third parties is issued on form BCCMTM/acron/BP/14. BCCMTM have their own forms for notifying to the depositor the refusal (see (c)(i) above) of a microorganism and for notifying to the depositor that they are not in a position to furnish samples. BCCMTM use the standard forms in preference to the other official notifications.

Unofficial Notifications to the Depositor. Although BCCMTM confirm receipt of the microorganisms sent to them, that does not mean that they have accepted them for deposit. If the viability test gives a positive result, BCCMTM communicate the result, on request, by telephone or telefax, together with the deposit number of the microorganism before issuing the official documents.

Supply of Information to a Patent Agent. BCCMTM request the depositor to communicate to them, in the interest of all concerned, the name and address of his patent agent. On request, they will provide to the patent agent a copy of the receipt and of the viability statement.

(iii) Converting a Previous Deposit

Deposits that were not made under the Budapest Treaty may be converted by the original depositor into deposits under that Treaty, whether or not the microorganisms were originally deposited for the purposes of patent procedure. Any earlier deposit--even if made free of charge--is subject, at the time of conversion, to the storage fee normally charged for deposits made under the Budapest Treaty. The administrative requirements for conversion are the same as those that must be met for an original deposit made under the Budapest Treaty.

(iv) Making a New Deposit

When making a new deposit, the depositor must complete form BCCMTM/acron/BP/2 and furnish copies of the documents referred to in Rule 6.2. The receipt and the viability statement with respect to a new deposit are issued on the compulsory “international forms” BCCMTM/acron/BP/5 and BCCMTM/acron/BP/9, respectively.

2. Furnishing of Samples

(a) Requests for Samples

BCCMTM will inform third parties of the procedure to be followed in order to make a proper request. For those requests requiring proof of the right to receive samples, BCCMTM will supply the requesting parties copies of the standard request form BCCMTM/acron/BP/12 or of the request forms used by a given industrial property office (insofar as such office has transmitted the relevant forms to BCCMTM).

Notwithstanding any entitlement by a third party to receive samples under patent regulations, BCCMTM will conserve the samples of potentially hazardous microorganisms until the requesting party has proven that it holds an authorization to handle such organisms. Likewise, they will only furnish samples of a microorganism to recognized microbiological laboratories and not to private addresses. In the case of requests from abroad, BCCMTM will assume that the requesting party has satisfied its own country's requirements with regard to importation.

All samples of microorganisms furnished by BCCMTM will be taken from the batches they have prepared themselves. Samples of genetic material in the form of a preparation of isolated material, animal and human cell lines and hybridomas will come from the material furnished by the depositor.

(b) Notification of the Depositor

When BCCMTM furnish samples of deposited microorganisms to third parties, they will notify the respective depositors on standard form BCCMTM/acron/BP/14, unless the depositors have waived their right to receive such notification.

(c) Cataloguing of Budapest Treaty Deposits

BCCMTM will not list, in the catalogs it publishes, the deposits made under the Budapest Treaty.

3. Schedule of Fees

Belgian francs

Genetic material, bacteria, filamentous fungi, yeasts:

(a)	<u>Storage</u> ¹	20,000
(b)	Issuance of viability statement	
	– if the viability test is to be carried out	2,000
	– based on the last viability test	800
(c)	<u>Furnishing of samples</u>	2,000
	<u>Communication of information under Rule 7.6</u>	800
(d)	Issue of attestation under Rule 8.2	800

Human cells, animal cells, hybridomas:

(a)	<u>Storage</u> ²	45,000
(b)	<u>Issuance of viability statement</u>	
	– if the viability test is to be carried out (on a case-by-case basis)	3,000 (minimum)
	– based on the last viability test	800
(c)	<u>Furnishing of sample</u>	4,000
(d)	<u>Communication of information under Rule 7.6</u>	800
(e)	<u>Issue of attestation under Rule 8.2</u>	800

Fees do not include the cost of communication.

¹ The fee for storage of microorganisms which cannot be stored other than in active culture or for mixtures (defined or identifiable, see 1(a) above) will be determined on a case-by-case basis after prior negotiation with the depositor.

² Including mycoplasma contamination test.

4. Guidance for Depositors

Depositors are reminded that all requests or deposits should be dealt with directly with the BCCMTM Collection concerned. They may also obtain the necessary forms from that Collection.

BCCMTM have published a brochure describing their overall activities and a manual on how to deposit for patent purposes with BCCMTM. They are of course available to potential depositors to provide any detailed information by telephone ((322) 2383411), telefax ((322) 2305912) or letter.

BG – BULGARIA

NATIONAL BANK FOR INDUSTRIAL MICROORGANISMS AND CELL CULTURES (NBIMCC)

125, Tsarigradsko chaussee blvd., block 2
1113 SOFIA
Bulgaria

E-mail: nbimcc@olb.net

(See *Industrial Property*, 1987, p. 363; 1993, p. 167; *Industrial Property and Copyright*, 1995, p. 43.)

1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

Bacteria, actinomycetes, microscopic fungi, yeasts, animal cell lines, animal viruses, plant viruses and microorganisms containing plasmids.

(b) Technical Requirements and Procedures

(i) Form and Quantity

For each kind of microorganism, the minimum number of replicates that must be supplied by the depositor when making his deposit and the form in which they must be submitted are as follows:

bacteria and fungi	3 agar stabs (minimum viable count 10^7)
fungi	3 agar stabs (minimum viable count 10^6)
yeasts	(minimum viable count lyophilized 10^7)
animal viruses	10 lyophilized (minimum titre 10^4 infective units)
animal cell lines and hybridomas	10 frozen in liquid nitrogen (minimum 5×10^6 viable cells per vial)
plasmids (in host)	3 lyophilized (minimum 5×10^6)

(ii) Time Required for Viability Testing

The minimum and maximum lengths of time required for testing the viability of the various kinds of microorganisms accepted by the NBIMCC are as follows:

animal viruses	from 2 to 20 days
bacteria	from 10 to 35 days
animal cell lines	from 1 to 7 days
fungi	from 30 to 45 days
hybridomas	not specified
plasmids	from 15 to 30 days
yeasts	from 15 to 30 days

(iii) Depositor Checks and Renewal of Stocks

The NBIMCC prepares its own batches of bacteria, fungi, yeasts and plasmids by subculturing material supplied by the depositor. New batches are prepared from the depositor's original material for the renewal of stocks. The depositor is required to check the authenticity of batches prepared by the NBIMCC at the time of deposit (but not thereafter). The NBIMCC nevertheless stores original material supplied by the depositor.

(c) Administrative Requirements and Procedures

(i) General

Language. The official language of the NBIMCC is Bulgarian. Communications are also accepted in English, French and Russian.

Contract. The NBIMCC does not enter into a written contract with the depositor defining the liabilities of either party.

Import and/or Quarantine Regulations. The kinds of microorganisms accepted by the NBIMCC are not subject to quarantine regulations. However, import regulations must be observed in respect of certain kinds of microorganisms accepted by the NBIMCC. The average time to obtain an import permit is about six months and information in this connection can be obtained from the National Center of Biotechnology, Ilia Shosse 16, Sofia and from the Patent Office of the Republic of Bulgaria, 52B, Dr. G.M. Dimitrov Blvd., 1113 Sofia.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. The depositor is required to complete the NBIMCC accession form for patent deposit.

Official Notifications to the Depositor. No form is used. Letters are used for all notification purposes.

Unofficial Notifications to the Depositor. If requested, the NBIMCC will telephone or telex the date of deposit and accession number after the microorganism has been received, but before the official receipt is issued. Similarly, the NBIMCC will communicate the result of the viability test before the viability statement is issued.

Supply of Information to a Patent Agent. The NBIMCC does not ask the depositor for the name and address of his patent agent. However, if requested, the NBIMCC will supply copies of the receipt and the viability statement to either the depositor or his patent agent.

(iii) Converting a Previous Deposit

Deposits made outside the provisions of the Budapest Treaty may be converted to deposits under the Budapest Treaty, provided they were originally made for patent purposes. No fee is charged for converting a deposit made outside the Budapest Treaty to a “Budapest deposit.” The administrative requirements for conversion are the same as those to be met in respect of an original deposit made under the Treaty.

(iv) Making a New Deposit

In addition to completing a standard form and to supplying copies of the relevant documents specified in Rule 6.2, the depositor is required to indicate any additional properties of and references about the microorganism.

2. Furnishing of Samples

(a) Requests for Samples

The NBIMCC advises third parties of the correct procedures to follow to make a valid request.

The NBIMCC furnishes a sample of a dangerous microorganism without receiving confirmation that the requesting party can comply with the relevant safety requirements and regulations, on the assumption that it is the responsibility of the requesting party to ensure that he complies with such requirements. When responding to a request from overseas, the NBIMCC checks that the requesting party has met the import requirements of his own country.

(b) Notification of the Depositor

Depositors are notified when samples of their microorganism have been furnished to third parties.

(c) Cataloguing of Budapest Treaty Deposits

At present, the NBIMCC does not publish a catalog.

3. Schedule of Fees

	Leva
(a) <u>Storage</u>	
– for the deposit and its storage for 30 years	1,000
– for prolongation of the deposit for each five-year period	150
(b) <u>Issuance of viability statement</u>	
(c) <u>Furnishing of samples</u>	100

4. Guidance for Depositors

The NBIMCC does not have notes available for the guidance of prospective depositors.

CA – CANADA

BUREAU OF MICROBIOLOGY, HEALTH CANADA (BMHC)

1015 Arlington Street
Winnipeg, Manitoba, R3E 3R2
Canada

Telephone: (204) 789-2070

Facsimile: (204) 789-2097

Internet home page: <http://www.hc.sc.gc.ca/hpb.lcdc/bmb/index/html>

(See *Intellectual Property Laws and Treaties*, 1998, p. 65.)

1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

The BMHC will accept for deposit: animal viruses including Level 1, 2 and 3 pathogenic viruses but excluding Level 4 viruses, Level 1, 2 and 3 bacteria, all bacteriophages, all mammalian cell lines, and all cloned genes. Fungi (relating to human health), hybridomas, protozoa, yeasts (relating to human health), plasmid and phage vectors, libraries and other rDNA material will also be accepted. In the case of deposits consisting of or containing recombinant DNA molecules, the risk group associated with the deposit should be determined as described in the 1980 National Institutes of Health “Guidelines for Research Involving Recombinant DNA Molecules” (US Department of Health and Human Services, Bethesda, Maryland, United States of America). The BMHC must be informed, in advance, of the containment level required of all submissions of Level 2 and 3 organisms.

The BMHC reserves the right to refuse submissions which, in the view of the Curator:

- (ii) fall outside of those listed above (i.e. submission is not of a kind to which the assurances furnished under Rule 3.1(b)(iii) or 3.3 extend);
- (iii) the properties of the submission are such that BMHC does not possess the facilities to perform the tasks required under the Budapest Treaty;
- (iv) the deposit was received in a condition which precludes, for scientific reasons, the acceptance of the sample.

(b) Technical Requirements and Procedures

(1) Form and Quantity

The BMHC will only accept deposits which can be preserved without significant change to their properties by freezing or lyophilization. Deposits which cannot be preserved in this manner or can only be maintained in active culture may be accepted on an individual basis, with prior negotiation and determination of associated fees.

Depositors are encouraged to supply frozen or freeze-dried material. However, when possible, the BMHC will accept actively growing material, and preserve it by freezing or freeze-drying at an additional cost. In these cases a sample of the preserved material will be returned to the depositor for verification of properties. However, if the preserved material is viable but not acceptable (e.g., properties altered), a new deposit must be made, and the original deposit date will be void. Depositors are therefore urged to supply frozen or freeze-dried material prepared in their laboratory in order to avoid the possibility of this occurring.

The quantity of material required for the various types of deposits is as follows:

Microorganisms (including bacteria (either containing a plasmid or not containing a plasmid), bacteriophages, fungi, yeast and protozoa)	10 frozen (0.5 ml each) or freeze-dried samples
Plasmids and Vectors not in host (e.g., purified DNA, libraries and associated rDNA material)	25 vials (min. 100 ng each)
Animal Viruses	25 frozen (1 ml each) or freeze-dried samples
Cell Lines and Hybridomas	25 frozen samples (2 – 6 million cells each)

(ii) Time Required for Viability Testing

The time required for testing the viability of the different types of deposits is indicated below. However, depositors should be aware that in certain cases viability testing may take longer.

Bacteria	3 – 7 days
Fungi and yeasts	7 – 10 days
Cell lines, hybridomas and bacteriophages	7 – 10 days
Plasmid, phages and other rDNA ¹	7 – 10 days
Protozoa	10 or more days
Animal viruses	30 or more days

¹ If applicable “viability” of the deposit is determined by the ability of the material to successfully transform, infect or otherwise alter a host cell.

(iii) Depositor Checks and Renewal of Stocks

It is the responsibility of the depositor to furnish a sufficient quantity of the material for the specified period of time. If a culture or other biological material should become non-viable or be destroyed during the effective term of the deposit, it is the responsibility of the depositor to replace it with viable material. The BMHC may consider, for a fee, to replenish the material on behalf of the depositor, however, it is the responsibility of the depositor to authenticate the material prepared and to inform the BMHC of the results. Whichever method is used for renewal of stocks the BMHC will maintain a portion of the material originally submitted for deposit.

(c) Administrative Requirements and Procedures

(i) General

Language. The official languages of Canada and the BMHC are English and French. Communications in any other language are not accepted.

Contract. The BMHC does not enter into any written contract with the depositor defining the liabilities of either party, except in the case of certain dangerous organisms, where the depositor must agree to accept and handle them at his own risk. Also, by completing the BMHC BP/1 deposit form, the depositor foregoes any right to withdraw his deposit during the required storage period and accepts that the material will be distributed according to the relevant patent requirements.

Import and/or Quarantine Regulations. The BMHC is subject to Canadian and international regulations governing the importation, exportation and transportation of infectious substances. Information relating to the importation and safe handling of infectious substances affecting humans can be obtained through the Health Canada web site (<http://www.hc-sc.gc.ca/hpb/lcdc/biosafety/index.html>), or by contacting the Director, Office of Biosafety, Laboratory Centre for Disease Control, Ottawa, Ontario, K1A 0L2, tel: (613) 957-1779. Information regarding veterinary pathogens and permits may be obtained from Agriculture and Agri-Food Canada, 59 Camelot Drive, Nepean, Ontario K1A 0Y9, tel.: (613) 952-8000. Inquiries regarding the transportation of regulated material should be directed to the Director General of the Transport of Dangerous Goods Directorate of Transport Canada, Canada Building, 344 Slater Street, 14th Floor, Ottawa, Ontario K1A 0N5, tel.: (613) 998-0517. These agencies may also be able to assist with information relating to the relevant regulations in countries other than Canada however it is advised that the appropriate agencies for the country in question be contacted.

It is essential that the depositor contact the BMHC in advance of submitting a deposit which may be subject to these regulations to ensure that the appropriate documentation is obtained. This is particularly important for deposits made from outside of Canada. Failure to do so could result in the deposit being refused entry into the country.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. The BMHC requires that depositors complete the Statement In The Case Of An Original Deposit (form BP/1) in order to meet the requirements of the Budapest Treaty. In the event of later amendments to the scientific description and/or proposed taxonomic designation the depositor must complete the BMHC form BP/14. In the case of a new deposit made under Article 4 of the Budapest Treaty the depositor must complete form BP/2.

Official Notifications to the Depositor. Notifications of receipt and viability are issued on the mandatory international forms (BP/4 and BP/9, respectively). Attestation of receipt of an amendment of the scientific description and/or proposed taxonomic designation is issued on form BP/7. If requested, notification of furnishing of a sample to a third party is issued on form BP/8.

Unofficial Notifications to the Depositor. If requested, the BMHC will convey the date of deposit and accession number after the submission has been received but before the official receipt is issued. Notification of the result of the viability testing is only communicated through official correspondence.

Supply of Information to a Patent Agent. If requested, the BMHC will supply copies of the receipt and viability statement to the depositor's patent agent.

(iii) Converting a Previous Deposit

The BMHC does not permit the conversion of deposits not originally made for patent purposes for Budapest Treaty deposits. The procedures outlined above for making a deposit must be followed in all cases.

(iv) Making a New Deposit

In the advent that a new deposit is submitted the BMHC requires that the Statement In The Case Of A New Deposit (form BP/2) be completed. The deposit will retain its initial deposit number and date as long as the replacement deposit is viable, the deposit is made within three months of receiving notification from the BMHC and the BMHC receives a statement signed by the depositor alleging that the newly deposited material is the same as that originally deposited. Charges for viability testing are required for new deposits.

2. Furnishing of Samples

(a) Requests for Samples

The BMHC makes available samples of deposited material only to parties who are so entitled under the terms of the Budapest Treaty and its Regulations. The BMHC will provide requesting parties with request forms (as appropriate) or assist with obtaining the necessary forms required for their request.

The BMHC accepts deposits of organisms which are potentially hazardous and may be subject to health and safety regulations. When such organisms are requested the BMHC will withhold issuing samples until it has confirmed that the requesting party can comply with such regulations. In certain cases, the BMHC may also require that the requesting party sign an assurance of acceptance of responsibility before agreeing to release a sample. In order to expedite the release of such samples it is therefore advisable that all requests be accompanied by documentation attesting to the fact that the requesting party has the facilities required for, and agrees to the regulations governing the handling of the requested material.

The BMHC attempts to ensure that the correct documentation is obtained prior to the shipping of the material requested. However, it is the responsibility of the requesting party to obtain all of the necessary permits which may be required.

(b) Notification of the Depositor

Unless the right to be so notified has been waived, the BMHC will notify the depositor on form BP/8 each time a sample of the deposit is furnished to a third party.

(c) Cataloguing of Budapest Treaty Deposits

At this time the BMHC does not publish a catalog of its culture collection.

3. Schedule of Fees

	Canadian dollars
Viability statement	200
30 years storage	800
30 years of notification of requesting parties	500
Furnishing of samples	50 + shipping
Attestation of receipt of revised scientific description	50
Communication of scientific description to 3rd party	50
Additional 5 years of storage beyond 30 years	125

This list is of base prices. Deposits requiring special conditions or care are subject to surcharges. All prices are quoted in Canadian dollars and are subject to the Canadian Goods and Services Tax at the current rate.

4. Guidance for Depositors

The BMHC is in the process of preparing a detailed information package for depositors. Until this is available all inquiries should be directed to the main office.

CN – CHINA

CHINA CENTER FOR TYPE CULTURE COLLECTION (CCTCC)

Wuhan University
WUHAN 430072
China

Telephone: (027) 788 2712-2319

Telefax: (027) 788 3833

Internet home page: <http://www.im.ac.cn/imcas/junbao.html>

(See *Industrial Property and Copyright*, 1995, p. 235.)

1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

Algae, animal viruses,¹ bacteria, cell lines, fungi, hybridomas, plant cell cultures, plant viruses, plasmids (a) in a host, (b) as an isolated DNA preparation, phages, seeds and yeasts, EXCEPT:

- microorganisms having properties which are or may be greatly dangerous to human health, animals and plants, or the environment;
- microorganisms containing recombinant DNA molecules which belong to a hazard classification higher than II as defined in the Safety Handling Rules of Gene Engineering of the Scientific and Technological Commission of the People's Republic of China, December 1993.

Notwithstanding the foregoing, the CCTCC reserves the right to refuse to accept any microorganism for deposit which, in the opinion of the Director, presents an unacceptable risk or is technically unsuitable to handle. The CCTCC will accept organisms without significant change to or loss of their properties after long-term freezing, freeze-drying or liquid nitrogen. Nucleic acid preparations and phages may be accepted if the depositor certifies that they pose no hazard when handled by normal laboratory procedures and the depositor supplies suitable material for preservation.

¹ If certain animal viruses require viability testing in an animal host, which the CCTCC may be unable to provide, and for plant viruses which cannot be mechanically inoculated, the depositor is required to consult the CCTCC in advance.

(b) Technical Requirements and Procedures

(i) Form and Quantity

Bacteria, fungi and yeasts (including those containing plasmids), algae and phages must be submitted for deposit as lyophilized preparations; however, agar stab or slant cultures are also accepted. Viruses that cannot be lyophilized should be frozen. Plasmids in the form of an isolated DNA preparation must be furnished in freeze-dried form or precipitated in alcohol. Bacteriophages and plasmids need to be sent together with a suitable host, if such a host is not available in the public collection of the CCTCC. Plant cell cultures can only be deposited in the form of callus or suspension cultures with non-differentiated growth. Animal cell cultures are accepted in the form of frozen cultures. The material for deposit must be free from contamination by foreign organisms. Before being dispatched to the CCTCC, animal cell cultures must be examined to ensure that they are free from viruses.

All replicates of the microorganisms to be deposited should be from the same batch of lyophilized or frozen preparations.

The minimum number of replicates that must be provided by the depositor when making his deposit is as follows:

algae, bacteria, fungi, plant viruses, yeasts	5
bacteriophages (at least 10^8 pfu/ml)	5 X 0,5 ml (free-cell lysate)
animal cell lines, animal viruses, hybridomas, plasmids (DNA at least 20 meg/tube)	11
seeds	2,500

(ii) Time Required for Viability Testing

The average length of time required for testing the viability of the various kinds of microorganisms accepted by the CCTCC is given below, but depositors should realize that in some cases viability testing may take longer, as indicated by the figures in brackets:

bacteria	3 days (or up to 14 days)
algae, fungi, yeasts	5 days (or up to 20 days)

animal cell lines, hybridomas, bacteriophages, plasmids ¹	7 days (or up to 14 days)
animal viruses, plant cell cultures, seeds	21 days (or up to 30 days)
plant viruses	no date as yet

(iii) Depositor Checks and Renewal of Stocks

The CCTCC prepares its own batches in lyophilized or frozen form at the time of deposit by subculturing the microorganisms supplied by the depositor. New batches are prepared from these as necessary thereafter for the renewal of diminishing stocks. The CCTCC generally does not prepare its own batches of animal and plant viruses, plasmids, seeds, and some animal cell lines, hybridomas and plant tissue cultures. When stocks of material are depleted by the furnishing of samples, the CCTCC will ask the depositor to make a new deposit.

Whichever method is used for preparing batches of samples for distribution, the CCTCC nevertheless stores a portion of the original material supplied by the depositor.

(c) Administrative Requirements and Procedures

(i) General

Language. The official language of the CCTCC is Chinese. Communications in English are also accepted.

Contract. The CCTCC does not enter into a written contract with the depositor defining the liabilities of either party, except in the case of certain dangerous organisms, where the depositor must agree to accept and handle them at his own risk. Also, by signing the CCTCC deposit forms, the depositor surrenders any right to withdraw his deposit during the required storage period and accepts that the microorganisms will be distributed according to the relevant patent requirements.

Import and/or Quarantine Regulations. Overseas depositors must contact the CCTCC in advance for advice about the shipping of their microorganisms. The microorganisms are all subject to import and/or quarantine regulations. In such cases, the prospective depositor must supply the species name of the microorganisms, whereupon the CCTCC will apply the import license and/or quarantine to the concerned organizations in China. Obtaining such a permit usually takes one or two weeks. After obtaining it, the CCTCC will inform the depositor or his agent as to how to send the cultures to the CCTCC.

¹ For plasmids, "viability" testing consists in inserting the plasmid into a host. If the host is transformed, the "viability test" is regarded as positive.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. Depositors are required to complete the application and accession form used by the CCTCC for deposits under the Budapest Treaty, which is model form BP/1. In the event of a later indication or amendment of the scientific description and/or proposed taxonomic designation, and a request for attestation that the CCTCC has received such information, the depositor must complete the equivalent of model form BP/7.

Official Notifications to the Depositor. The receipt and viability statements are issued on mandatory “international forms” BP/4 and BP/9, respectively. Attestation of receipt of a later indication or amendment of the scientific description and/or proposed taxonomic designation is issued on the equivalent of model form BP/8. Notification of the furnishing of samples to third parties is issued on model form BP/14. Individual correspondence is used rather than standards forms for other official notifications.

Unofficial Notifications to the Depositor. If requested, the CCTCC will telephone or telefax the date of deposit and accession number after the microorganism has been received, but before the official receipt is issued. The CCTCC will similarly communicate the result of the viability test before the viability statement is issued, but only after the viability test has been done and has given a positive result. A fee of \$10 is charged for each service for the overseas depositors.

Supply of Information to a Patent Agent. The CCTCC routinely asks the depositor to give the name and address of his patent agent. If requested, the CCTCC will supply copies of the receipt, the viability statement and any other information to both the depositor and his patent agent.

(iii) Converting a Previous Deposit

Deposits made outside the provisions of the Budapest Treaty may be converted by the original depositor to Budapest Treaty deposits, whether or not they were originally deposited for patent purposes. However, any deposits previously made free of charge are subject, on conversion, to storage fee normally levied for Budapest Treaty deposits. The administrative requirements for conversion are the same as those to be met in respect of an original deposit made under the Treaty, except that requirements relating to import and/or quarantine procedures do not apply.

(iv) Making a New Deposit

The depositor is required to complete model form BP/2 when making a new deposit, and to supply copies of the relevant documents required by Rule 6.2 of the Regulations under the Budapest Treaty. The receipt and viability statements for a new deposit are issued on mandatory “international forms” BP/5 and BP/9, respectively.

2. Furnishing of Samples

(a) Requests for Samples

The CCTCC advises third parties of the correct procedures to follow in order to make a valid request. In the case of requests requiring proof of entitlement, the CCTCC will provide requesting parties with copies of model request form BP/12 and/or request forms used by individual industrial property offices (where it has been supplied with such forms).

Notwithstanding any entitlement of third parties to receive samples under patent regulations, the CCTCC will withhold samples of organisms that are subject to health and safety regulations until the requesting party has shown that he has a permit to work with such organisms. When responding to a request from overseas, the CCTCC must obtain an export permit from the concerned organizations in China, and assumes that the requesting party has met the import requirements of his own country.

Except for animal viruses, plasmids, seeds, and some animal cell lines, hybridomas and plant tissue cultures, the samples of microorganisms furnished by the CCTCC are from batches of its own preparations of the microorganisms.

(b) Notification of the Depositor

Depositors are notified on model form BP/14 when samples of their microorganisms have been furnished to third parties.

(c) Cataloguing of Budapest Treaty Deposits

If the depositor or a competent patent office instructs the CCTCC to make samples of a microorganism available to anyone, that organism is listed in the next published CCTCC catalog. All microorganisms that are the subject of granted and published Chinese patents are listed in the CCTCC catalog.

3. Schedule of Fees

	US dollars
(a) <u>Storage</u>	
– algae, bacteria, fungi, yeasts	500
– animal and plant viruses, cell lines, hybridomas, phages, plant cell cultures, plasmids, seeds	700

US dollars

- | | | |
|-----|---|--|
| (b) | <u>Issuance of viability statement</u> | |
| | – algae, bacteria, fungi, yeasts | 50 |
| | – cells lines, hybridomas, animal and plant viruses, phages, plant cell cultures, plasmids, seeds | fee to be decided on an individual basis |
| (c) | <u>Furnishing of samples</u> | |
| | – algae, bacteria, fungi, yeasts | 40 |
| | – animal and plant viruses, cell lines, hybridomas, phages, plant cell cultures, plasmids, seeds | 70 |
| (d) | <u>Other fees</u> (communication, permits for import and/or export, and quarantine, etc.) | according to real cost |

Fees are subject to Value Added Tax where applicable.

4. Guidance for Depositors

The CCTCC has published a leaflet describing its overall activities and it is available to possible depositors to provide detailed information by telephone, telefax, or letter.

CN – CHINA

CHINA GENERAL MICROBIOLOGICAL CULTURE COLLECTION CENTER (CGMCC)

China Committee for Culture Collection of Microorganisms
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BEIJING 100080
China

Telephone: 2555614

Telefax: 2560912

Internet home page: <http://www.1.im.ac.cn/typecc/junzhong/en.html>

(See *Industrial Property and Copyright*, 1995, p. 233.)

1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

The kinds of microorganisms that may be deposited with the CGMCC are as follows, with the exception of pathogenic microorganisms of Risk Group 1 (Chinese classification):

– bacteria, actinomycetes, filamentous fungi, yeasts, single-cell algae, mycoplasma, animal viruses,¹ plant viruses,¹ phages, plasmids and mixtures of microorganisms.

The CGMCC will accept deposits consisting of or containing recombinant DNA molecules. The highest acceptable physical containment level is P2 as described by the US Department of Health and Human Services, National Institutes of Health, in “Guidelines for Research Involving Recombinant DNA Molecules.”

At present, the CGMCC does not accept the following biological material for deposit:

- plant seeds, protozoa, animal cell lines, plant cell lines;
- microorganisms which are restricted from importing according to Chinese law;
- microorganisms whose conservation involves hazards deemed to be excessive.

As a general rule, the CGMCC will accept only strains that can be placed in a culture under conditions technically feasible for the collection concerned and conserved, other than in continuous vegetative activity, without inducing significant changes in their characteristics.

¹ Certain animal viruses may require viability testing in an animal host which the CGMCC may be unable to provide. In such cases, the deposit cannot be accepted. Plant viruses which cannot be mechanically inoculated cannot be accepted, either.

Exceptionally, the CGMCC may accept deposits that cannot be conserved other than by active culture, but acceptance of such a deposit will have to be decided, and the relevant fee determined, on a case-by-case basis after prior negotiation with the potential depositor.

Notwithstanding the foregoing, the CGMCC reserves the right to reject or accept for deposit any material which, in the opinion of the Director, represents a risk that is either unacceptable or too difficult to handle.

(b) Technical Requirements and Procedures

(i) Form and Quantity

Cultures of microorganisms are accepted by the CGMCC in any form. The minimum number of replicates that must be provided by the depositor when making his deposit is as follows:

bacteria, actinomycetes, yeasts, filamentous fungi, phages, mycoplasma, single cell algae, mixtures of microorganisms	5
viruses, plasmids (not cloned into a host)	25

(ii) Time Required for Viability Testing

The average length of time required for testing the viability of the various kinds of microorganisms accepted by the CGMCC is given below, but depositors should realize that in some cases viability testing may take longer, as indicated by the figures in brackets:

bacteria	3 days (or up to 14 days)
actinomycetes, yeasts	5 days (or up to 20 days)
filamentous fungi	6 days (or up to 30 days)
phages, single cell algae	7 days (or up to 14 days)
plasmids ¹	8 days (or up to 10 days)
animal viruses	21 days (or up to 30 days)
plant viruses	no date as yet

¹ For plasmids, "viability" testing consists in inserting the plasmid into a host. If the host is transformed, the "viability test" is regarded as positive.

(iii) Depositor Checks and Renewal of Stocks

The CGMCC prepares its own lyophilized and/or frozen batches at the time of deposit of bacteria, actinomycetes, yeasts, filamentous fungi, phages, single cell algae and, in some cases, viruses, by subculture of, or directly from, active material supplied by the depositor. New batches are prepared as necessary for the renewal of diminishing stocks. The CGMCC stores and distributes lyophilized material supplied by the depositor, if this is his wish. The CGMCC generally does not prepare its own batches of animal viruses and plasmids. In such cases, when stocks of material are depleted by the furnishing of samples, the CGMCC will ask the depositor to make a new deposit.

The CGMCC requires the depositor to check the authenticity of its lyophilized preparations. The viability statement issued by the CGMCC contains a section in which the depositor can record the result of this test. If the depositor does not inform the CGMCC of the results of this test within three months, the CGMCC assumes that its preparations are equivalent to the depositor's original deposit.

Whichever method is used for preparing batches of samples for distribution, the CGMCC stores a portion of the original prepared and deposited material.

(c) Administrative Requirements and Procedures

(i) General

Language. The working languages of CGMCC are Chinese and English.

Contract. The CGMCC does not enter into any written contract with the depositor defining the liabilities of either party, except in the case of certain dangerous organisms, where the depositor must agree to accept and handle them at his own risk. Also,

- to supply all the necessary information requested by the CGMCC;
- to pay all the necessary fees;
- not to withdraw the deposit during the required storage period;
- to authorize the CGMCC to supply samples in accordance with the requirements of the patent procedure applicable at the time.

Import and/or Quarantine Regulations. For the deposit from abroad, the CGMCC must obtain an import permit from the Chinese departments concerned for the import of microorganisms into China, which takes about seven days (or up to 14 days). The CGMCC will notify the depositor or depositor's patent agent when it gets the import permit. Depositors must pay for quarantine.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. Depositors are required to complete CGMCC form BP/1 “Budapest Treaty Deposits” in all cases. The CGMCC does not require a special form to be completed in the event of a later indication or amendment of the scientific description and/or proposed taxonomic designation, or for a request for attestation that the CGMCC has received such information.

Official Notifications to the Depositor. The receipt and viability statements are issued on mandatory “international forms” BP/4 and BP/9, respectively. Notification of release of a sample to a third party is issued on form BP/14. Standard forms are not used for other official notifications.

Unofficial Notifications to the Depositor. If requested, the CGMCC will telephone or telex the date of deposit and accession number after the microorganisms have been received, but before the official receipt is issued. A fee of \$10 is charged for this service. The CGMCC similarly will telephone or telex the result of the viability test before the official viability statement is issued.

Supply of Information to a Patent Agent. If requested, the CGMCC will supply copies of the receipt and viability statements to the depositor’s patent agent.

(iii) Converting a Previous Deposit

Deposits made outside the provisions of the Budapest Treaty may be converted by the original depositor to Budapest Treaty deposits, whether or not they were originally deposited for patent purposes. However, any deposits previously made free of charge are subject on conversion to the storage fees normally levied for Budapest Treaty deposits. The administrative requirements for conversion are the same as those to be met in respect of an original deposit made under the Budapest Treaty, except that requirements relating to import and/or quarantine procedures do not apply.

(iv) Making a New Deposit

The CGMCC may accept a new deposit under Article 4 of the Budapest Treaty and Rule 6.2 of the Regulations under the Treaty. The CGMCC does not require the depositor to complete a standard form when making a new deposit, but he is asked to supply an acknowledgment that the new deposit is the same as the original deposit (Article 4), and to send copies of the relevant documents (Rule 6.2).

2. Furnishing of Samples

(a) Requests for Samples

The CGMCC will furnish samples to interested industrial property offices, to the depositor or parties with the authorization of the depositor, to parties legally entitled under Rule 11.3 of the Regulations under the Budapest Treaty.

The CGMCC advises third parties of the correct procedures to be followed in making a valid request. In the case of requesters requiring proof of entitlement, the CGMCC provides them with copies of model request form BP/12.

The CGMCC will withhold samples of organisms that are subject to health and safety regulations until it has confirmed that the requesting party can comply with such regulations. Also, in some cases a permit from the Chinese departments concerned is required to work with certain organisms considered potentially very dangerous in China, and a requesting party in China must obtain such a permit before he can receive a sample.

When requests are received from abroad, the CGMCC presumes that the individual concerned is familiar with his country's import requirements.

Except for animal viruses and plasmids, the CGMCC furnishes samples of its own preparations of the deposited microorganism.

(b) Notification of the Depositor

Unless he has waived his right to be so notified, the CGMCC notifies the depositor on CGMCC form BP/14 each time a sample of his deposit is furnished to a third party.

(c) Cataloguing of Budapest Treaty Deposits

If the depositor or a competent patent office instructs the CGMCC to make samples of a microorganism available to anyone, that organism is listed in the next published CGMCC catalog. All microorganisms that are the subject of patents granted and published by the Patent Office of the People's Republic of China are listed in the CGMCC catalog.

3. Schedule of Fees

	US dollars
(a) <u>Storage</u>	500
(b) <u>Issuance of viability statement</u>	
– bacteria (without plasmids), fungi, yeasts, single-cell algae, mycoplasma	50
– animal and plant viruses, bacteria with plasmids	fee decided on an individual basis
(c) <u>Furnishing of samples of CGMCC cultures</u>	50
(d) <u>Communication of information</u>	20

4. Guidance for Depositors

The CGMCC publishes a brochure giving details of its requirements and practices for the deposit of cultures for patent purposes.

CZ – CZECH REPUBLIC

CZECH COLLECTION OF MICROORGANISMS (CCM)

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Czech Republic

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Telefax: (05) 74 01 08
Internet home page: <http://www.sci.muni.cz/ccm/ccmang.htm>

(See *Industrial Property*, 1992, pp. 211 and 213; 1994, pp. 167 and 393.)

1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

Bacteria (including actinomycetes), filamentous fungi, yeast-like microorganisms, yeasts, capable of long-term preservation without any substantial change of their initial properties, plasmids in a host.

The CCM accepts for deposit only those bacteria, filamentous fungi, yeast-like microorganisms and yeasts which, pursuant to the “Laboratory Biosafety Manual” (World Health Organization, Geneva 1983), belong to hazard group I or II.

Microorganisms having special requirements for cultivation which the CCM is not technically capable of carrying out shall not be accepted.

Cultures without scientific description as well as cultures which cannot be identified shall not be accepted.

When depositing strains containing a plasmid, the CCM shall require information on the plasmid and its host strain in respect of their properties and classification (i.e., group P1, P2, P3 or P4). The CCM shall accept only plasmids belonging to group P1.

(b) Technical Requirements and Procedures

(i) Form and Quantity

Bacteria and fungi, including those containing plasmids, are accepted by the CCM as lyophilized or actively growing cultures, except agar plate cultures (these are prone to become damaged in transport).

The depositor is required to provide two lyophilized or agar cultures when making his deposit.

(ii) Time Required for Viability Testing

The average time required for testing the viability of various microorganisms accepted by the CCM is five days, but the depositor should realize that in some cases, especially with slow growing microorganisms, viability testing may take as long as 14 days.

(iii) Depositor Checks and Renewal of Stocks

The CCM prepares its own lyophilized and/or frozen batches of bacteria and fungi at the time of deposit by subculturing material supplied by the depositor. New batches are prepared from these as necessary thereafter for the renewal of diminishing stocks. The depositor is required to test for authenticity samples from all batches of his microorganisms prepared by the CCM.

Whichever method is used for preparing batches of samples for distribution, the CCM always keeps original material supplied by the depositor.

(c) Administrative Requirements and Procedures

(i) General

Language. The official language of the CCM is Czech. Communications are also accepted in English.

Contract. The CCM does not enter into any written contract with the depositor defining the liabilities of either party but, by signing the CCM deposit forms, the depositor surrenders any right to withdraw his deposit during the required storage period and accepts that the microorganisms will be distributed according to the relevant patent requirements.

Import and/or Quarantine Regulations. At present, there are no kinds of microorganisms in the CCM accepted under the Budapest Treaty which may be subject to import or quarantine regulations. But this may be changed in the future.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. Depositors are required to complete form CCM-BP/1 (the equivalent of model form BP/1) which is the accession form used for Budapest Treaty deposits.

Official Notifications to the Depositor. The receipt and viability statement are issued on mandatory “international forms” BP/4 and BP/9, respectively, both in Czech and English. Notification of furnishing of a sample to a third party is issued on model form BP/14. The CCM uses its own standard letters for other official notifications.

Unofficial Notifications to the Depositor. If requested, the CCM will telephone or telefax the date of deposit and the accession number before the official receipt is issued, but only after a positive viability test has been obtained.

Supply of Information to a Patent Agent. The CCM does not routinely ask the depositor for the name and address of his patent agent. However, if requested, the CCM will send copies of the receipt and viability statement to both the depositor and his patent agent.

(iii) Converting a Previous Deposit

Deposits made outside the provisions of the Budapest Treaty may be converted by the original depositor to deposits under the Budapest Treaty only if they were originally made for patent purposes. The administrative requirements for conversion are similar to those to be met in respect of an original deposit made under the Treaty.

All conversions are subject to the storage fee normally levied for Budapest Treaty deposits.

(iv) Making a New Deposit

The depositor is required to complete the equivalent of model form BP/2 when making a new deposit, and to supply copies of the relevant documents required by Rule 6.2. The receipt and viability statement for a new deposit are issued on mandatory “international forms” BP/5 and BP/9.

2. Furnishing of Samples

(a) Request for Samples

The CCM advises third parties of the correct procedures to follow in order to make a valid request. In the case of requests requiring proof of entitlement, the CCM will provide requesting parties with copies of model request form BP/12 and/or request forms used by individual industrial property offices (where it has been supplied with such forms).

When responding to requests from overseas, the CCM will ask the requesting party to provide an import permit if it knows that one is required for that particular country.

All samples furnished by the CCM are from batches of its own preparations.

(b) Notification of the Depositor

Depositors are notified on model form BP/14 when samples of their microorganism have been furnished to third parties.

(c) Cataloguing of Budapest Treaty Deposits

The CCM does not list Budapest Treaty deposits in its published catalog.

3. Schedule of Fees

	Czech crowns
(a) <u>Storage</u>	14,000
(b) <u>Issuance of viability statement</u>	400
(c) <u>Furnishing of samples</u>	1,000 (plus cost of transport)

4. Guidance for Depositors

At present the CCM does not have specific written notes for the guidance of depositors, but is always ready to offer advice by telephone or correspondence.

DE – GERMANY

DEUTSCHE SAMMLUNG VON MIKROORGANISMEN UND ZELLKULTUREN GmbH (DSMZ)

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(See *Industrial Property*, 1981, pp. 220 and 221; 1988, pp. 139 to 141; 1990, pp. 71 and 249 to 251; 1991, pp. 108 to 110; 1994, pp. 68 to 70; *Industrial Property and Copyright*, 1996, pp. 161 and 162; *Intellectual Property Laws and Treaties*, 1998, pp. 67 and 68.)

1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

Bacteria, including bacteria containing plasmids, fungi, including yeasts, bacteriophages, plasmids (a) in a host, (b) as an isolated DNA preparation, plant viruses, plant cell cultures, animal and human cell cultures, murine embryos. The following phytopathogenic microorganisms are not accepted for deposit: *Coniothyrium fagacearum*, *Endothia parasitica*, *Gloeosporium ampelophagum*, *Septoria musiva*, *Synchytrium endobioticum*.

The DSMZ accepts for deposit only those microorganisms which, pursuant to the notices of the “*Berufsgenossenschaft der chemischen Industrie*” (German Trade Association of the Chemical Industry) on “*Sichere Biotechnologie, Eingruppierung biologischer Agenzien*” (“Safe biotechnology, classification of biological agents”) (bacteria B006, fungi B007, viruses B004, cell cultures B009) or Directive 93/88 EEC on the protection of workers from risks related to exposure to biological agents at work (OJ No. L268/71, dated 21.10.1993), belong to hazard group 1 or 2. The Directive is regularly updated. If the relevant group is not known, information can be obtained from the DSMZ.

Genetically manipulated organisms and isolated DNA must be processable as S1 or S2, or Class 1 or 2 organisms, respectively, in accordance with safety levels 1 or 2 of the “*Gesetz zur Regelung der Gentechnik*” (Genetic Engineering Act) (BGBl. pp. 2067-2083, dated 21.12.1993) or in accordance with Council Directive 98/81/EC amending Directive 90/219/EEC on the contained use of genetically modified microorganisms (OJ No. L330, dated 26.10.1998).

Plant viruses which cannot be multiplied through mechanical infection of plants cannot be accepted for deposit.

Plant cell cultures can only be deposited in the form of callus or suspension cultures with non-differentiated growth. The material for deposit must be free from contamination by foreign organisms.

Animal and human cell cultures cannot be accepted for deposit if they are contaminated with viruses or other foreign organisms (particularly mycoplasma). Please note that the DSMZ requires about two weeks for carrying out the necessary check for mycoplasma contamination.

Before preservation of the murine embryos by the depositor and subsequent dispatch to the DSMZ, information concerning the method to be used must be obtained from the DSMZ.

The DSMZ reserves the right to refuse for deposit material which in its view represents an unacceptable hazard or which it is not in a position to process.

In all instances, it must be possible to preserve the deposited material by lyophilization or storage in liquid nitrogen or by some other method of long-term preservation without significant change.

(b) Technical Requirements and Procedures

(i) Form and Quantity

The DSMZ has the following special requirements for the form of culture in which the microorganisms should be submitted for deposit. Bacteria and fungi should, where possible, be deposited in the form of two active cultures. Lyophilized cultures are also accepted. Bacteriophages should be deposited in minimum quantities of 2 x 5 ml having a minimum titre of 1×10^9 pfu pro ml. Plasmids as isolated DNA preparations should be in a minimum quantity of 2 x 20 [micro] g. Bacteriophages and plasmids need to be sent together with a suitable host, if such a host is not available in the public collection of the DSMZ. Plant viruses should be deposited in the form of dried or frozen material along with the host's seeds, unless the host is generally available. 100 [micro] l of serum suitable for immunoelectron microscopy should also be deposited for the purity and identity test. When hybridomas for antibody testing of plants are deposited, the antigen (not pathogen) necessary for the specificity test should be deposited at the same time. Plant cell cultures can only be deposited in the form of callus or suspension cultures with non-differentiated growth. In the case of plant cell cultures, active cultures in the form of a callus (four petri dishes) or suspension (three culture vessels) or frozen cultures (18 cryoampoules) should be deposited. In the case of animal and human cell cultures, frozen cultures should be deposited in 12 ampoules, each containing at least 5×10^6 cells. Murine embryos should be deposited in 12 ampoules, each containing at least 15-20 embryos. The material for deposit must be free from contamination by foreign organisms. Before being dispatched to the DSMZ, animal and human cell cultures must be examined to ensure they are free of viruses. Cultures should be sent in appropriate containers.

The deposit must be accompanied by the appropriate form duly completed (Form DSMZ-BP/1: Original Deposit; DSMZ-BP/2: New Deposit; or DSMZ-BP/3: New Deposit

with Another International Depository Authority, in English or German). Depositors can obtain these from the DSMZ (separate forms are to be used for bacteria and fungi, bacteriophages, isolated plasmid DNA, plant viruses, plant cell cultures, animal and human cell cultures and murine embryos). The fee for storage mentioned in Rule 12.1(a)(i) of the Regulations under the Budapest Treaty must be paid.

(ii) Time Required for Viability Testing

The average time required for testing the viability of the various kinds of microorganisms accepted by the DSMZ is given below, but depositors should realize that in some cases, especially with slow growing microorganisms, viability testing may take longer, as indicated by the figures in brackets:

bacteria, yeasts, bacteriophages and plasmids	2 days (or up to 3 weeks)
fungi	3 days (or up to 3 weeks)
plant viruses	2 weeks
plant cell cultures	3 to 4 weeks
human and animal cell cultures (including test for contamination with mycoplasma)	2 weeks
murine embryos	1 week

(iii) Depositor Checks and Renewal of Stocks

The DSMZ prepares its own lyophilized and/or frozen batches of bacteria, fungi and plant cell cultures at the time of deposit by subculturing material supplied by the depositor (but not from plasmids, bacteriophages, plant viruses, animal and human cell cultures or murine embryos). New batches are prepared from these as necessary thereafter for the renewal of diminishing stocks. The depositor is required to test for authenticity samples from all batches of his microorganism prepared by the DSMZ.

Despite the methods used for preparing batches of samples for distribution, the DSMZ nevertheless stores a portion of the original material supplied by the depositor, if the culture supplied allows this.

(c) Administrative Requirements and Procedures

(i) General

Language. The official language of the DSMZ is German. Communications are also accepted in English. Correspondence in French is accepted, except in the case of forms.

Contract. The DSMZ does not enter into a written contract with the depositor defining the liabilities of either party but, by signing the DSMZ deposit form, the depositor surrenders any right to withdraw his microorganism during the required storage period.

Import and/or Quarantine Regulations. In very few cases import regulations apply to the kinds of microorganisms accepted by the DSMZ. In such cases, the depositor must supply the species name of the microorganism, whereupon the DSMZ will apply to obtain the necessary permit. The kinds of microorganisms accepted by the DSMZ are not subject to quarantine regulations. Further information about import requirements may be obtained from: Bundesminister für Ernährung, Landwirtschaft und Forsten, Rochusstrasse 1, D-53123 Bonn, Germany.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. Depositors are required to complete form DSMZ-BP/1 (the equivalent of model form BP/1) which is the accession form used for Budapest Treaty deposits. The DSMZ uses separate forms for the deposit of bacteria or fungi, bacteriophages, plasmids, plant viruses, plant cell cultures, animal and human cell cultures, and murine embryos. In the event of a later indication or amendment of the scientific description and/or proposed taxonomic designation, and a request for attestation that the DSMZ has received such information, the depositor must complete the equivalent of model form BP/7.

Official Notifications to the Depositor. The receipt and viability statement are issued on mandatory "international forms" BP/4 and BP/9, respectively, both in German and English. Attestation of receipt of a later indication or amendment of the scientific description and/or proposed taxonomic designation is issued on the equivalent of model form BP/8. Notification of the furnishing of samples to third parties is issued on model form BP/14. Standard forms are not used for other official notifications.

Unofficial Notifications to the Depositor. If requested, the DSMZ will telefax the date of deposit and accession number before the official receipt is issued, but only after the viability test has been done and has given a positive result. The DSMZ will similarly communicate the results of the viability test before the viability statement is issued.

Supply of Information to a Patent Agent. The DSMZ does not routinely ask the depositor for the name and address of his patent agent. However, if requested, the DSMZ will send copies of the receipt and viability statement to both the depositor and his patent agent.

(iii) Converting a Previous Deposit

Deposits made outside the provisions of the Budapest Treaty may be converted by the original depositor to Budapest Treaty deposits, whether or not they were originally made for patent purposes. However, in the case of deposits previously made for scientific purposes and which are already generally available from the DSMZ, the depositor is requested to authorize the DSMZ to continue to make them so available and to waive his right to be notified of the release of samples. If the depositor is unwilling to accede to this request, he must make another deposit of the same organism under the Budapest Treaty. These constraints do not apply to deposits previously made for patent purposes or to deposits made confidentially for safekeeping. Any deposit previously made free of charge is subject, on conversion, to the storage fee normally levied for Budapest Treaty deposits. With the exceptions noted above, the administrative requirements for conversion are the same as those to be met in respect of an original deposit made under the Treaty.

(iv) Making a New Deposit

The depositor is required to complete the equivalent of model form BP/2 when making a new deposit, and to supply copies of the relevant documents required by Rule 6.2. The receipt and viability statement for a new deposit are issued on mandatory “international forms” BP/5 and BP/9.

2. Furnishing of Samples

(a) Requests for Samples

The DSMZ advises third parties of the correct procedures to follow in order to make a valid request. In the case of requests requiring proof of entitlement, the DSMZ will provide requesting parties with copies of model request form BP/12 and/or request forms used by individual industrial property offices (where it has been supplied with such forms).

Model request form BP 13 is used in connection with requests for deposited microorganisms where the responsible patent office has communicated lists of the accession numbers given by the IDA to deposits of microorganisms referred to in the said patents.

Notwithstanding any entitlement of third parties to receive samples under patent regulations, the DSMZ will withhold samples of potentially hazardous microorganisms until the requesting party has provided evidence that he is allowed to work with such organism. When responding to requests from overseas, the DSMZ will ask the requesting party to provide an import permit if it knows that one is required for that particular country.

All samples of bacteria and fungi furnished by the DSMZ are from batches of its own preparations of the microorganism.

(b) Notification of the Depositor

Depositors are notified on model form BP/14 when samples of their microorganism have been furnished to third parties.

(c) Cataloguing of Budapest Treaty Deposits

The DSMZ does not list Budapest Treaty deposits in its published catalogue.

3. Schedule of Fees

	Deutsche Mark	Euro
I. <u>Bacteria, fungi, bacteriophages, plasmids, plant viruses:</u>		
(a) <u>Storage under Rule 12.1(a)(i)</u>	1,350	690.24
(b) <u>Conversion of a deposit made outside the Budapest Treaty into a deposit according to the Budapest Treaty</u>	1,350	690.24
(c) <u>Prolongation of the duration of the storage beyond that provided by Rule 9, per year¹</u>	45	23.00
d) <u>Issuance of viability statement</u>		
– where a viability test is also requested	180	92.03
– on the basis of the last viability test	60	30.68
(e) <u>Furnishing of samples</u>	180	92.03
(f) <u>Communication of information under Rule 7.6</u>	60	30.68
(g) <u>Attestation referred to in Rule 8.2</u>	60	30.68

¹ See WIPO document BP/A/II/11, p. 4, paragraph 29.

	Deutsche Mark	Euro
II. <u>Plant cell cultures:</u>		
(a) <u>Storage under Rule 12.1(a)(i)</u>	2,500	1,278.23
(b) <u>Conversion of a deposit made outside the Budapest Treaty into a deposit according to the Budapest Treaty</u>	2,500	1,278.23
(c) <u>Prolongation of the duration of the storage beyond that provided by Rule 9, per year</u>	80	40.90
(d) <u>Issuance of viability statement</u>		
– where a viability test is also requested	200	102.25
– on the basis of the last viability test	60	30.68
(e) <u>Furnishing of samples</u>	200 (plus current freight costs)	102.25
(f) <u>Communication of information under Rule 7.6</u>	60	30.68
(g) <u>Attestation referred to in Rule 8.2</u>	60	30.68
III. <u>Human and animal cell cultures, murine embryos:</u>		
(a) <u>Storage under Rule 12.1(a)(i)</u>	2,400	1,227.10
(b) <u>Conversion of a deposit made outside the Budapest Treaty into a deposit according to the Budapest Treaty</u>	2,400	1,227.10
(c) <u>Prolongation of the duration of the storage beyond that provided by Rule 9, per year</u>	80	40.90
(d) <u>Issuance of viability statement</u>		
– where a viability test is also requested	200	102.25
– on the basis of the last viability test	60	30.68

	Deutsche Mark	Euro
(e) <u>Furnishing of samples</u>	200 (plus current freight costs)	102.25
(f) <u>Communication of information under Rule 7.6</u>	60	30.68
(g) <u>Attestation referred to in Rule 8.2</u>	60	30.68

For all customers, the fees under (a), (b), (c), (d), (f) and (g) (services provided within Germany) are subject to VAT, currently at the rate of 7%, which is also payable where samples are furnished (e) to requesting parties in Germany.

Turnover tax, again currently at the rate of 7%, must also be charged on EC orders not quoting a VAT registration number.

A processing fee of DEM 40 to cover bank charges is payable on all foreign invoices.

4. Guidance for Depositors

The DSMZ provides specific written notes for the guidance of prospective depositors. In addition, it is always ready to give advice by telephone.

ES – SPAIN

COLECCION ESPAÑOLA DE CULTIVOS TIPO (CECT)

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Internet home page: <http://www.cib.csic.es/~cedig/CECT.html>

(See *Industrial Property*, 1992, p. 163; *Industrial Property and Copyright*, 1997, p. 240.)

1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

Bacteria, including actinomycetes, which may be preserved, without any significant alteration of their properties, by freezing or freeze-drying, and which belong to a Risk Group lower than 2 according to the definition of the UK Advisory Committee on Dangerous Pathogens (ACDP) 1984, "Categorisation of Pathogens according to Hazard and Categories of Containment," (HMSO, London, ISBN 0-11-883761-3).

Filamentous fungi, including yeasts, with the exception of strains known to be human, plant and animal pathogens, which may be preserved by freezing or freeze-drying without any significant alteration of their properties.

For the time being, the CECT does not accept the following biological material for deposit:

- anaerobic microorganisms (except *Clostridium*)
- algae and cyanobacteria
- plasmids
- embryos
- protozoa
- animal cell lines
- plant cell lines
- mycoplasma
- plant seed
- viruses
- bacteriophages

Notwithstanding the foregoing, the CECT reserves the right to reject or accept for deposit any material which, in the opinion of the Director, represents a risk that is either unacceptable or too difficult to handle.

(b) Technical Requirements and Procedures

(i) Form and Quantity

Bacteria and fungi (including those containing plasmids) are accepted in freeze-dried form in ampoules or in the form of active cultures in agar solution. The depositor should send the CECT five ampoules or agar samples of each strain.

(ii) Time Required for Viability Testing

On average, the time required for testing the viability of bacterial samples is three days (or up to 14 days), and for fungus strains six days (or up to 30 days). The depositor has to take into account that, in certain cases, viability testing can take a great deal of time, as indicated by the bracketed figures.

(iii) Depositor Checks and Renewal of Stocks

The CECT prepares its frozen or freeze-dried batches by subculturing the materials supplied by the depositor. While the batches are being completed, further batches are prepared on the basis of frozen or freeze-dried samples from the first batch prepared. Whatever the method used for the preparation of batches or samples for distribution, the CECT freeze-dries, freezes and retains a portion of the original material supplied by the depositor. The depositor is requested to prove the authenticity of all the freeze-dried and frozen samples prepared by the CECT.

(c) Administrative Requirements and Procedures

(i) General

Language. The official languages of the CECT are Spanish and English.

Contract. The application to the CECT that the depositor has to complete is a contract under which the depositor undertakes:

- to supply all the necessary information requested by the CECT;
- to pay all the necessary fees;
- to indemnify the CECT against any claim that may be made on it as a result of the sending of samples, except where the claims are due to negligence on the part of the CECT;

- not to withdraw the deposit during the time required for its period of storage;
- to authorize the CECT to supply samples in accordance with the requirements of the patent procedure applicable at the time.

Import and/or Quarantine Regulations. The packaging and dispatch of CECT cultures is done in accordance with the laws of the Convention of the Universal Postal Union. Depositors from abroad apply to the CECT in advance for information on the correct procedure for the dispatch of samples. Spain does not allow infectious substances to be sent by air mail, with the exception of samples originating in the United Kingdom and sent direct to the CECT. The samples may be sent direct to the CECT from other countries as freight in accordance with IATA rules.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. Depositors have to complete the application and accession forms used by the CECT for deposits under the Budapest Treaty, which are equivalent to model form BP/1.

Official Notifications to the Depositor. The receipt and viability statement are issued on mandatory “international forms” BP/4 and BP/9, respectively. Attestation of receipt of a later indication or amendment of the scientific description and/or proposed taxonomic designation is issued on model form BP/8. Notification of the furnishing of samples to third parties is issued on model form BP/14. Individual correspondence is used rather than standard forms for other official notifications.

Unofficial Notifications to the Depositor. If requested, the CECT communicates the date of deposit and the accession number by telephone after the microorganism has been received but before the official receipt is issued. In that case however the depositor is informed that the information is provisional and subject to the outcome of the viability tests. The CECT likewise communicates the finding of the viability test before the viability statement is issued.

Supply of Information to a Patent Agent. The CECT routinely asks the depositor for the name and address of his patent agent and, if so requested, supplies copies of the receipt, the viability statement and any other information to both the depositor and his patent agent.

(iii) Converting a Previous Deposit

Deposits made outside the provisions of the Budapest Treaty may be converted by the original depositor to deposits under the Budapest Treaty, whether or not they were originally made for patent purposes. Any deposit previously made free of charge is subject, on conversion, to the payment of the storage fee specified in this technical memorandum, and also to whatever fees may be payable for successive updating. With the above exceptions, the administrative requirements for conversion are the same as those to be met for an original deposit effected under the Treaty. The date of deposit for such samples will then be that of the conversion.

(iv) Making a New Deposit

The depositor will be required to complete model form BP/2 when making a new deposit, and to supply copies of the relevant documents required by Article 12. The receipt and the viability statement for a new deposit are issued on mandatory “international forms” BP/5 and BP/9.

2. Furnishing of Samples

(a) Requests for Samples

The CECT advises third parties of the correct procedures to be followed in making a valid request. In the case of requests requiring proof of entitlement, the CECT provides requesters with copies of model request form BP/12. When requests are received from abroad, the CECT presumes that the individual concerned is familiar with his country's import requirements.

All samples of bacteria and fungi furnished by the CECT are taken from batches prepared by itself.

(b) Notification of the Depositor

The depositor is informed on model form BP/14 when samples of his microorganisms have been sent to third parties.

(c) Cataloguing of Budapest Treaty Deposits

The CECT issues lists of deposits under the Budapest Treaty in its catalogs only with the express written consent of the depositor.

3. Schedule of Fees

	Pesetas
(a) <u>Storage</u>	
– original deposits	70,000
– new deposits	10,000
(b) <u>Issue of viability statement</u>	10,000
(c) <u>Furnishing of a sample</u>	6,000

- (d) Communication of information under Rule 7.6 6,000

4. Guidance for Depositors

For the moment the CECT does not publish specific information for the guidance of prospective depositors, but is always willing to provide information by telephone or correspondence.

FR – FRANCE

COLLECTION NATIONALE DE CULTURES DE MICRO-ORGANISMES (CNCM)

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(See *Industrial Property*, 1984, p. 240; 1989, p. 25; *Industrial Property and Copyright*, 1996, p. 42.)

1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

Animal cell cultures, including human cell lines, genetically modified cell lines and hybridomas, bacteria (including actinomycetes), bacteria containing plasmids, filamentous fungi, yeasts, viruses, including bacteriophages, EXCEPT:

- plant tissue cultures;
- microorganisms whose manipulation calls for physical containment levels of P3 or P4 as described in the National Institutes of Health “Guidelines for Research Involving Recombinant DNA Molecules” and “Laboratory Safety Monograph”;
- microorganisms liable to require viability testing that the CNCM is technically not able to carry out;
- mixtures of undefined and/or unidentifiable microorganisms.

The CNCM reserves the right to refuse any cell culture which, according to the curator, involves an unacceptable risk or is not suitable, for technical reasons, for handling and any microorganism for security reasons: specific risks to human beings, animals, plants and the environment. In cases where a microorganism cannot be lyophilized, the CNCM must be consulted in advance about the conditions for acceptance. The highest acceptable containment level is generally P2 as described in the National Institutes of Health “Guidelines for Research Involving Recombinant DNA Molecules” and “Laboratory Safety Monograph.” However, in exceptional cases and by special arrangement microorganisms requiring a containment level of P3 may be accepted.

GB – UNITED KINGDOM

CULTURE COLLECTION OF ALGAE AND PROTOZOA (CCAP)

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(See *Industrial Property*, 1982, p. 239; 1986, p. 431; 1987, p. 175; 1990, p. 251.)

1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

Freshwater and terrestrial algae and free-living protozoa, with the exception of parasitic protozoa not pathogenic to man or domestic animals, which can be maintained by in vitro culture (INSTITUTE OF FRESHWATER ECOLOGY); marine algae, other than large seaweeds; free-living protozoa (DUNSTAFFNAGE MARINE LABORATORY). Microorganisms containing recombinant DNA molecules must not require physical containment levels higher than level II as defined by the UK Advisory Committee on Genetic Manipulation, Guidance Note 15 (Health and Safety Executive, Baynards House, 1 Chepstow Place, London W2 4TF). Other microorganisms must not require containment facilities more stringent than those appropriate to Hazard Group 3 as defined by the UK Advisory Committee on Dangerous Pathogens (ACDP), 1984, "Categorisation of Pathogens according to Hazard and Categories of Containment" (HMSO, London, ISBN 011 883761 3).

(b) Technical Requirements and Procedures

(i) Form and Quantity

Microorganisms should be submitted for deposit as liquid or agar slope cultures. The minimum number of replicates that must be provided by the depositor when making his deposit is six. Algal cultures must contain a minimum of 10^2 to 10^4 cell/ml, depending on the species, and three plants in the case of seaweeds. The minimum number of cells in cultures of protozoa must be decided by negotiation.

(ii) Time Required for Viability Testing

The average length of time required for testing the viability of algae and protozoa accepted by the CCAP is seven days, but depositors should realize that in some cases viability testing may take as long as 35 days.

(iii) Depositor Checks and Renewal of Stocks

Except where the depositor's original material is preserved by freezing, as is the case with some algae, the CCAP prepares its own batches of the microorganism at the time of deposit by subculturing material supplied by the depositor. New batches are prepared from these as necessary thereafter for the renewal of diminishing stocks. In cases where original material has been cryopreserved, stocks are renewed by subculturing these or by asking the depositor for a new deposit. The depositor is required to test for authenticity samples from the first (but not any subsequent) batch of his microorganism prepared by the CCAP.

Except for cryopreserved strains, the CCAP does not store original material supplied by the depositor.

(c) Administrative Requirements and Procedures

(i) General

Language. The official language of the CCAP is English. Communications in any other language are not accepted.

Contract. The CCAP application form, which the depositor is required to complete, constitutes a contract by which he is bound:

- to provide all necessary information requested by the CCAP;
- to replace the microorganism at his expense if the CCAP is no longer able to furnish samples of it;
- to pay all necessary fees;

- to indemnify the CCAP against any claims which may be brought against it as a consequence of the release of samples, unless such claims result from negligence on the part of the CCAP;
- not to withdraw his deposit during the required storage period;
- to authorize the CCAP to furnish samples according to the applicable patent requirements.

When a microorganism has been accepted for deposit, the CCAP notifies the depositor and reminds him that he is bound by the terms and conditions of its contract.

Import and/or Quarantine Regulations. The kinds of microorganisms accepted by the CCAP are not subject to import or quarantine regulations.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. As well as the CCAP application form referred to in (i), above, depositors are required to complete the CCAP accession form for patent deposits. The CCAP does not require a special form to be completed in the event of a later indication or amendment of the scientific description and/or proposed taxonomic designation, or for a request for attestation that the CCAP has received such information.

Official Notifications to the Depositor. The receipt and viability statement are issued on mandatory “international forms” BP/4 and BP/9, respectively. The CCAP has its own standard forms notifying the depositor of acceptance of a microorganism (see (i), above) or of refusal to accept a microorganism, but standard forms are not used for other official notifications.

Unofficial Notifications to the Depositor. If requested, the CCAP will telephone or telex the date of deposit and accession number after the microorganism has been received, but before the official receipt is issued. The CCAP will similarly communicate the result of the viability test before the viability statement is issued.

Supply of Information to a Patent Agent. The CCAP routinely asks the depositor for the name and address of his patent agent. If requested, the CCAP will supply copies of the receipt and viability statement to both the depositor and his patent agent.

(iii) Converting a Previous Deposit

The CCAP does not have any deposits made for patent purposes outside the provisions of the Budapest Treaty and does not consider Rule 6.4(d) applicable in other cases.

(iv) Making a New Deposit

The CCAP does not require the depositor to complete a standard form when making a new deposit, but he must supply copies of the relevant documents and declarations required by

Rule 6.2. The receipt and viability statement for a new deposit are issued on mandatory “international forms” BP/5 and BP/9, respectively.

2. Furnishing of Samples

(a) Requests for Samples

The CCAP advises third parties of the correct procedures to follow in order to make a valid request. In the case of requests requiring proof of entitlement, the CCAP will provide requesting parties with copies of model request form BP/12 and/or request forms used by individual industrial property offices (where it has been supplied with such forms).

The CCAP furnishes samples in the belief that it is the responsibility of the requesting party to ensure that he complies with any relevant health and safety requirements. When responding to requests from overseas, the CCAP assumes that the requesting party has met the import requirements of his own country.

Except where material originally supplied by the depositor has been cryopreserved, as is the case with some algae, samples of microorganisms furnished by the CCAP are from batches of its own preparations of the microorganism.

(b) Notification of the Depositor

Depositors are notified by letter when samples of their microorganism have been furnished to third parties.

(c) Cataloguing of Budapest Treaty Deposits

The CCAP does not list Budapest Treaty deposits in its published catalog.

3. Schedule of Fees

Pounds Sterling

(a) Storage

- (i) cryopreserved strains
- (ii) other methods of maintenance

600
(fee to be decided on an individual basis)

(b) Issuance of viability statement

50

	Pounds Sterling
(c) <u>Furnishing of samples</u>	40 (plus actual cost of carriage)
(d) <u>Issuance of an attestation under Rule 8.2</u>	20

Fees are subject to Value Added Tax where applicable.

4. Guidance for Depositors

The CCAP does not yet have notes available for the guidance of prospective depositors.

GB – UNITED KINGDOM

EUROPEAN COLLECTION OF CELL CULTURES (ECACC)

Vaccine Research and Production Laboratory
Public Health Laboratory Service
Centre for Applied Microbiology and Research
PORTON DOWN
Salisbury, Wiltshire SP4 0JG
United Kingdom

Telephone: (1980) 61 2100
Telex: 47683 PHCAMR G
Internet home page: <http://www.camr.org.uk/frame.htm>

(See *Industrial Property*, 1984, p. 271; 1985, pp. 163 and 299; 1987, p. 147; 1990, p. 373; *Industrial Property and Copyright*, 1996, p. 147.)

1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

Animal cell cultures, including human cell lines, genetically modified cell lines and hybridomas that can be preserved without significant change to or loss of their properties by freezing and long-term storage; viruses capable of assay in tissue culture; plant cell suspension cultures; eukaryotic and viral recombinant DNA as naked DNA or cloned into a host organism; bacteria; pathogenic yeasts and fungi; pathogenic protozoa.

Organisms up to and including ACDP Category 3¹ and ACGM Category 3² are accepted for deposit by the Collection. The type of viruses accepted for deposit has been expanded to include ACDP Category 4.

Notwithstanding the foregoing, the ECACC reserves the right to refuse any material for deposit which in the opinion of the Curator presents an unacceptable risk or is technically unsuitable to handle. The ECACC will accept organisms which do not significantly change after long-term liquid nitrogen freezing or freeze-drying. A statement regarding potential pathogenicity and storage conditions is required when a deposit is made.

¹ Advisory Committee on Dangerous Pathogens, "Categorisation of Pathogens according to Hazard and Categories of Containment," HMSO, London, 1984.

² Advisory Committee on Genetic Manipulation, HSE Note 7, HMSO, London, 1988.

(b) Technical Requirements and Procedures

(i) Form and Quantity

Animal Cell Cultures. Material submitted to the ECACC for deposit must be in the form of frozen cultures. The ECACC may refuse deposits which have not been packed in sufficient dry ice to keep them frozen during transit. The minimum number of replicates that must be provided by the depositor when making his deposit is 12. All animal cell cultures must contain at least 4×10^6 cells/ampoule.

Plant Cell Cultures. Deposits are accepted in the form of frozen ampoules. The ECACC can provide a cryopreservation service with validation for each deposit. In this case the depositor must provide cultures three months in advance of the intended deposit date to enable sufficient time to optimize cryopreservation protocols and validation of recovered cultures by the depositor. Cell cultures are accepted on condition that they can be preserved without significant change or loss of properties by freezing and long-term storage. The minimum number of ampoules (all prepared at the same time) that must be provided by the depositor is 12, containing recoverable cultures which must be replaced, if required.

Recombinant DNA. Deposits are accepted in the form of frozen ampoules of a host organism containing plasmid or phage or naked plasmid or phage DNA. Growing cultures can be received on agar and as frozen ampoules produced by the ECACC by special arrangement. Plasmids and bacteriophage are accepted on condition that they can be preserved without significant change or loss of properties by freezing and long term storage. The minimum number of ampoules (all prepared at the same time) that must be provided by the depositor is 12, containing a culturable quantity of organisms which must be replaced, if required. Naked DNA should be deposited frozen in an appropriate solution e.g. 10mM, 1mM EDTA (pH7.5) in quantities suitable for electrophoretic analysis.

(ii) Time Required for Viability Testing

The average length of time required for testing the viability of the various kinds of microorganisms accepted by the ECACC is given below, but depositors should realize that in some cases viability testing may take longer, as indicated by the figures in brackets:

viruses	21 days (or up to 28 days)
animal cell cultures	14 days (or up to 21 days)
protozoa	variable
plant cell cultures	a minimum of 4 weeks
recombinant DNA	14 days

(iii) Depositor Checks and Renewal of Stocks

The ECACC generally does not prepare its own batches of the deposited organisms, and when stocks are depleted by the furnishing of samples, the depositor will be asked to make a

new deposit. However, by prior agreement with the depositor the ECACC may in some cases prepare its own batches from his material at the time of deposit and/or to renew diminishing stocks, although a portion of the original material supplied by the depositor is always kept. The depositor is asked to check for authenticity samples of batches prepared by the ECACC.

(c) Administrative Requirements and Procedures

(i) General

Language. The official language of the ECACC is English. Communications in any other language are not accepted.

Contract. The ECACC application form, which the depositor is required to complete, binds the depositor:

- to provide material only in the required form and quantity;
- to provide a statement of pathogenicity;
- to pay all necessary fees including all charges for the transportation of deposits to the ECACC;
- to observe the terms and conditions of the Budapest Treaty;
- to accept the terms and conditions of deposit in the ECACC.

Import and/or Quarantine Regulations. There are no import or quarantine regulations to be met in respect of the kinds of microorganisms accepted for deposit by the ECACC.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. As well as the ECACC application form referred to in (i), above, the depositor must complete an ECACC accession form and pathogenicity statement. Different sets of forms are used for different kinds of microorganisms and the depositor should ask the ECACC for the set of forms appropriate to the microorganism he wishes to deposit.

At least 48 hours before the microorganism is dispatched the ECACC must be informed of the number of ampoules being sent, the method of transportation and the estimated time of arrival. If dispatch is by air, the ECACC must be told the flight number and destination, waybill number and handling agent for delivery.

The ECACC does not require a special form to be completed in the event of a later indication or amendment of the scientific description and/or proposed taxonomic designation, or for a request for attestation that the ECACC has received such information.

Official Notifications to the Depositor. The receipt and viability statement are issued on mandatory “international forms” BP/4 and BP/9, respectively, but standard forms are not used for other official notifications.

Unofficial Notifications to the Depositor. If requested, the ECACC will telephone or telex the date of deposit and accession number after the microorganism has been received, but before the official receipt is issued. The result of the viability test will be communicated before the issue of a viability statement only where the viability of the deposit is unacceptably low.

Supply of Information to a Patent Agent. The ECACC does not routinely ask the depositor for the name and address of his patent agent. However, if requested, it will send copies of the receipt and viability statement to both the depositor and his patent agent.

(iii) Converting a Previous Deposit

Deposits made outside the provisions of the Budapest Treaty may be converted by the original depositor to Budapest Treaty deposits, whether or not they were originally deposited for patent purposes. However, any deposits previously made free of charge are subject, on conversion, to the storage fee normally levied for Budapest Treaty deposits. The administrative requirements for conversion are the same as those to be met in respect of an original deposit, except that requirements relating to shipping procedures do not, of course, apply.

(iv) Making a New Deposit

The depositor is required to complete the ECACC accession form and pathogenicity statement when making a new deposit, to send copies of the relevant documents and declaration (Rule 6.2) and to conform with the procedures mentioned previously in respect of shipping requirements.

2. Furnishing of Samples

(a) Requests for Samples

The ECACC does not advise requesting parties of the correct procedures to follow in order to make a valid request and does not supply copies of request forms in the case of requests requiring proof of entitlement. Such forms must be obtained from the relevant industrial property office.

Notwithstanding any entitlement of third parties to receive samples under patent regulations, the ECACC will withhold samples of potentially hazardous microorganisms until it has confirmed that the requesting party has the necessary containment facilities to handle such organisms. When responding to requests from overseas, the ECACC assumes that the requesting party has met the import requirements of his own country.

Samples furnished by the ECACC are usually from preparations supplied by the depositor.

(b) Notification of the Depositor

Depositors are notified by letter when samples of their microorganism have been furnished to third parties.

(c) Cataloguing of Budapest Treaty Deposits

The ECACC does not list Budapest Treaty deposits in its published catalog.

3. Schedule of Fees

	Pounds Sterling
I. <u>Cell lines, plant cell suspension cultures</u>	
(a) <u>Storage</u>	750
(b) <u>Issuance of viability statement</u>	60
(c) <u>Furnishing of samples</u>	80
II. <u>Viruses</u>	
(a) <u>Storage</u>	850
(b) <u>Issuance of viability statement</u>	150
(c) <u>Furnishing of samples</u>	100

III. Eukaryotic and viral recombinant DNA as naked DNA or cloned into a host organism

Pounds Sterling

- | | |
|--|-----|
| (a) <u>Storage</u> | 400 |
| (b) <u>Issuance of viability statement</u> | 60 |
| (c) <u>Furnishing of samples</u> | 80 |

IV. Pathogenic yeasts and fungi, pathogenic protozoa

- | | |
|--|-----|
| (a) <u>Storage</u> | 750 |
| (b) <u>Issuance of viability statement</u> | 60 |
| (c) <u>Furnishing of samples</u> | 80 |

V. Bacteria

- | | |
|--|-----|
| (a) <u>Storage</u> | 500 |
| (b) <u>Issuance of viability statement</u> | 60 |
| (c) <u>Furnishing of samples</u> | 80 |

The fees, plus Value Added Tax where applicable, are payable to the Public Health Laboratory Service Board.

4. Guidance for Depositors

Guidance for depositors is provided on the ECACC application form.

GB – UNITED KINGDOM

INTERNATIONAL MYCOLOGICAL INSTITUTE (IMI)

Bakeham Lane
Englefield Green
EGHAM, Surrey TW20 9TY
United Kingdom

Telephone: (0784) 470111
Telex: 9312102252
Telefax: (784) 470909
Internet home page: <http://www.imi-cabi.demon.co.uk>

(See *Industrial Property*, 1983, p. 83; 1989, pp. 51 and 171; 1992, p. 53.)

1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

Fungal isolates (including yeasts) and bacteria (including actinomycetes), other than known human and animal pathogens, that can be preserved without significant change to their properties by the methods of preservation in use.

The IMI accepts for deposit organisms up to and including ACDP Category 2, as described by the Advisory Committee on Dangerous Pathogens, "Categorisation of Pathogens according to Hazard and Categories of Containment," HMSO, London, 1990.

Notwithstanding the foregoing, the IMI reserves the right to refuse any material for deposit which in the opinion of the Curator presents an unacceptable risk or is technically unsuitable to handle. The IMI will accept organisms which do not significantly change after long-term nitrogen freezing or freeze-drying. A statement regarding potential pathogenicity and storage conditions is required when a deposit is made.

(b) Technical Requirements and Procedures

(i) Form and Quantity

The IMI prefers fungi to be submitted as healthy, clean, sporing cultures on agar slants suitable for preparing suspensions for freeze-drying and liquid nitrogen storage. The minimum number of replicates to be supplied by the depositor when making his deposit should be six.

(ii) Time Required for Viability Testing

The average length of time required for testing the viability of fungi accepted by the IMI is 14 days, but depositors should be aware that in some cases viability testing may take as long as 21 days.

(iii) Depositor Checks and Renewal of Stocks

Depending on the number and conditions of the cultures sent for deposit, the IMI either prepares frozen and lyophilized batches direct from the depositor's material or from subcultures derived from it. New batches are prepared as necessary for the renewal of diminishing stocks. The depositor is required to test for authenticity samples from all batches of his microorganism prepared by the IMI.

Whichever method is used for preparing batches of samples for distribution, the IMI nevertheless stores a portion of the original material supplied by the depositor.

(c) Administrative Requirements and Procedures

(i) General

Language. The official language of the IMI is English. Communications in any other language are not accepted.

Contract. The IMI application form (CC PF1), which the depositor is required to complete, constitutes a contract by which he is bound:

- to provide all necessary information requested by the IMI;
- to replace the microorganism at his expense if the IMI is no longer able to furnish samples of it;
- to pay all necessary fees;
- to indemnify the IMI against any claims which may be brought against it as a consequence of the release of samples, unless such claims result from negligence on the part of the IMI;
- not to withdraw his deposit during the required storage period;
- to authorize the IMI to furnish samples according to the appropriate patent requirements.

After the deposit and acceptance procedure is complete, the depositor is sent a standard letter (form CC PF3) reminding him of his contractual obligations.

Import and/or Quarantine Regulations. Plant pathogenic fungi not indigenous to the United Kingdom are subject to import regulations. The IMI holds a permit for the import of such organisms and will advise the depositor of any necessary procedures.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. As well as the IMI application form CC PF1 referred to in (i), above, depositors are required to complete the IMI accession form (CC PF2) for Budapest Treaty deposits. The IMI does not require a special form to be completed in the event of a later indication or amendment of the scientific description and/or proposed taxonomic designation, or for a request for attestation that the IMI has received such information.

Official Notifications to the Depositor. The receipt is issued on form CC PF3, which is the IMI version of the mandatory “international form” BP/4. The viability statement is issued on form CC PF5, which is the IMI version of the mandatory “international form” BP/9. A standard form (CC PF4) is used for notifying the depositor of refusal to accept a microorganism for deposit, but standard forms are not used for other official notifications.

Unofficial Notifications to the Depositor. The IMI acknowledges delivery of cultures, but this does not constitute acceptance. The IMI does not assign an accession number to the microorganism until it has been shown to be viable. After a positive result of the viability test has been obtained, the IMI will, if requested, telephone or telex this information along with the accession number before the issue of the official documentation.

Supply of Information to a Patent Agent. The IMI does not routinely ask the depositor for the name and address of his patent agent. However, if requested, the IMI will supply copies of the receipt and viability statement to both the depositor and his patent agent.

(iii) Converting a Previous Deposit

The IMI does not permit the conversion of deposits not originally made for patent purposes to Budapest Treaty deposits. Deposits previously made for patent purposes outside the provisions of the Treaty may be converted provided that the depositor supplies the IMI with a new sample of the deposited microorganism and checks the authenticity of all batches prepared from it. The administrative requirements for conversion are similar to those to be met in respect of an original deposit made under the Treaty. All conversions are subject to the storage fee normally levied for Budapest Treaty deposits, regardless of whether any fees had been paid previously in respect of those deposits.

(iv) Making a New Deposit

The depositor is required to complete model form BP/2 when making a new deposit and to send with it copies of the relevant documents required by Rule 6.2. The receipt and viability statement for a new deposit are issued on forms CC PF3 and CC PF5, which are the IMI versions of mandatory “international forms” BP/5 and BP/9, respectively.

2. Furnishing of Samples

(a) Requests for Samples

The IMI advises third parties of the correct procedures to follow in order to make a valid request. However, in the case of requests requiring proof of entitlement, the IMI does not supply copies of request forms; these must be obtained from the relevant industrial property office.

Notwithstanding any entitlement to receive samples under patent regulations, the IMI will furnish samples of plant pathogens that require a permit to be worked with in the United Kingdom only to third parties in the United Kingdom who have such a permit. The IMI will supply requesting parties who do not hold a permit with the necessary application form and will furnish samples when the requesting party confirms that he has obtained a permit. When responding to requests from overseas (other than from the United States of America), the IMI assumes that the requesting party has met the import requirements of his own country. In the case of requests from the United States of America, samples of plant pathogens are sent via the United States Department of Agriculture quarantine authority.

All samples furnished by the IMI are from batches of its own preparations which, whenever possible, have been made direct (i.e., without subculture) from material supplied by the depositor.

(b) Notification of the Depositor

Depositors are notified by letter when samples of their microorganism have been furnished to third parties.

(c) Cataloguing of Budapest Treaty Deposits

The IMI does not list Budapest Treaty deposits in its published catalog.

3. Schedule of Fees

	Pounds Sterling
(a) <u>Storage</u>	575
(b) <u>Issuance of viability statement</u>	75
(c) <u>Furnishing of samples</u>	45
(d) <u>Delivering an attestation under Rule 8.2</u>	15

Fees paid within the United Kingdom are subject to Value Added Tax at the current rate.

4. Guidance for Depositors

The IMI makes available detailed notes for the guidance of depositors.

GB – UNITED KINGDOM

NATIONAL COLLECTION OF FOOD BACTERIA (NCFB)*

AFRC Institute of Food Research
Reading Laboratory
Earley Gate
Whiteknights Road
READING, Berkshire RG6 2EF
United Kingdom

Telephone: (0734) 357 000
Telex: 9312102022
Telefax: (0734) 267 917

(See *Industrial Property*, 1990, p. 55; 1994, p. 203.)

* | The status of international depositary authority of the National Collection of Food
| Bacteria (NCFB) terminated on June 5, 1997 (See Budapest notification No. 155 of
| June 16, 1997, published in the June 1997 issue of *Industrial Property and Copyright*.)

GB – UNITED KINGDOM

NATIONAL COLLECTIONS OF INDUSTRIAL, FOOD AND MARINE BACTERIA (NCIMB)

23 St. Machar Drive
ABERDEEN AB2 1RY
Scotland
United Kingdom

Telephone: (44-1224) 273332
Telefax: (44-1224) 272 461
Internet home page: <http://www.ncimb.co.uk>

(See *Industrial Property*, 1982, pp. 121, 122 and 275; 1985, p. 25; 1986, p. 371; 1988, pp. 39 and 293; 1989, p. 24; 1990, p. 25; 1991, p. 108; *Industrial Property and Copyright*, 1995, p. 203; *Intellectual Property Laws and Treaties*, 1998, p. 56; 2000, p. 4.)

1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

Bacteria (including actinomycetes) yeasts, bacteriophages, plasmids (either cloned into a bacterial host or purified DNA preparations), including recombinants not greater than ACDP Group 2 or ACGM level 3, as the case may be, and provided that they can be preserved by freeze-drying or liquid nitrogen freezing without significant change to their properties.

NCIMB also accepts orthodox seeds, i.e. those that can be dried to a low moisture content and stored at temperatures lower than -20°C without damage. All arable crops and many small seeded tree species produce orthodox seeds.

Recalcitrant seeds, such as those of cocoa, rubber, some tropical fruits and large seeded woody species, which cannot be dried without damage, are not accepted.

The acceptance of seeds by NCIMB and the furnishing of samples thereof are subject at all times to the provisions of the Plant Health (Great Britain) Order 1987, including any future amendments or revisions of that Order.

NCIMB must be notified in advance of all intended deposits of seeds so that it may ensure that all relevant regulations are complied with. Any seeds received without prior notification may be destroyed immediately.

Notwithstanding the foregoing, NCIMB reserves the right to refuse any material for deposit which, in the opinion of the Curator, presents an unacceptable hazard or is technically too difficult to handle.

In exceptional circumstances NCIMB may accept deposits which can only be maintained in active culture, but acceptance of such deposits, and relevant fees, must be decided on an individual basis by prior negotiation with the prospective depositor.

(b) Technical Requirements and Procedures

(i) Form and Quantity

Bacteria and yeasts (including those containing plasmids) are accepted in any form except agar plate cultures (these are too easily damaged in transit). Bacteriophages should be supplied as cell-free lysates along with a suitable host. NCIMB prefers to receive sufficient lysate for direct freezing and distribution but, where this is not possible, smaller volumes from which NCIMB may produce its own lysates are acceptable (see below).

Naked plasmids should be submitted as DNA solutions. Seeds may be deposited either

- pre-dried under the IBPGR (International Board for Plant Genetic Resources) recommended conditions appropriate to the species and ready for immediate low-temperature storage,

or

- freshly harvested for drying by NCIMB, in which case they should be dispatched immediately after harvesting by express delivery in a hermetically sealed container.

In all cases, seeds should be fresh, healthy, undamaged, and free from soil or plant-derived debris. Less than 5% of the deposit should contain empty seeds.

Normally, a germination rate of at least 85% is required, but deposits may be accepted in certain circumstances where such a regeneration standard is impossible to achieve.

The minimum number of replicates to be supplied by the depositor when making his deposit is as follows:

bacteria and yeasts	2
Bacteriophages(at least 108 pfu/ml)	2 x 0.5 ml) cell-free or 1 x 10 ml) lysate
plasmids (DNA at least 20 mcg/ml)	1 x 10 ml

seeds	at least 250 seeds are required, but it is in the depositor's interest to send as many more as can be spared. (The IBPGR recommends a minimum of 4,000 for long-term storage and the United States Patent and Trademark Office may soon require a minimum of 2,500.)
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(ii) Time Required for Viability Testing

The average length of time required for testing the viability of the various kinds of microorganisms accepted by NCIMB is given below, but depositors should realize that in some cases viability testing may take longer, as indicated by the figures in brackets:

bacteria and yeasts	3 days (or up to 14 days)
bacteriophages	3 days (or up to 5 days)
plasmids ¹	5 days (longer in slow growing hosts)
seeds ²	depends entirely on the kind of seed

(iii) Depositor Checks and Renewal of Stocks

NCIMB prepares its own lyophilized and frozen batches of bacteria at the time of deposit by subculturing material supplied by the depositor. New batches are prepared from these as necessary thereafter for the renewal of diminishing stocks. NCIMB prepares its own frozen batches of bacteriophages by subculturing material supplied by the depositor in those cases where insufficient lysate has been provided for large enough batches to be prepared by direct freezing of the depositor's material. New batches are prepared from these as necessary for the renewal of diminishing stocks.

NCIMB prepares frozen batches of naked plasmids and dried batches of seeds direct from material supplied by the depositor. Diminishing stocks are renewed by asking the depositor to make a new deposit. The depositor is required to check for authenticity samples of all lyophilized and frozen batches prepared by NCIMB.

Whichever method is used for preparing batches of samples for distribution, NCIMB nevertheless freezes and stores a portion of the original material supplied by the depositor.

¹ For plasmids, "viability" testing consists of inserting the plasmid into a host. If the host is transformed, the "viability test" is regarded as positive.

² For seeds, "viability" testing means testing for germination.

(c) Administrative Requirements and Procedures

(i) General

Language. The official language of NCIMB is English. Communications in any other language are not accepted.

Contract. The NCIMB application form which the depositor is required to complete constitutes a contract by which he is bound:

- to provide all necessary information requested by NCIMB;
- to pay all necessary fees;
- to indemnify NCIMB against any claims which may be brought against it as a consequence of the release of samples, unless such claims result from negligence on the part of NCIMB;
- not to withdraw his deposit during the required storage period;
- to authorize NCIMB to furnish samples according to the applicable patent requirements.

When a microorganism has been accepted for deposit, NCIMB notifies the depositor and reminds him that he is bound by the terms and conditions of its contract.

Import and/or Quarantine Regulations. Most of the kinds of microorganisms accepted by NCIMB are not subject to import or quarantine regulations. However, non-indigenous plant pathogens and certain seeds require a license to be worked with in Scotland, and prospective depositors of plant pathogens or seeds should contact NCIMB in advance so that the necessary arrangements can be made. Failure to comply with this requirement may result in the immediate destruction by NCIMB of the material submitted. Further information may be obtained from the Department of Agriculture and Fisheries for Scotland, Agricultural Scientific Services, East Craigs, Edinburgh EH12 8NJ, Scotland, United Kingdom.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. As well as NCIMB application form referred to in (i), above, depositors are required to complete the NCIMB accession form for patent deposits. NCIMB does not require a special form to be completed in the event of a later indication or amendment of the scientific description and/or proposed taxonomic designation, or for a request for attestation that NCIMB has received such information.

Official Notifications to the Depositor. The receipt and viability statement are issued on mandatory “international forms” BP/4 and BP/9, respectively. Attestation of receipt of a later indication or amendment of the scientific description and/or proposed taxonomic designation is issued on model form BP/8. Notification of the furnishing of samples to third

parties is issued on model form BP/14. NCIMB has its own standard forms for notifying the depositor of acceptance of a microorganism (see (i), above) or of refusal to accept a microorganism, and for notifying the depositor of the inability of NCIMB to furnish samples. Individual letters, rather than standard forms, are used for other official notifications.

Unofficial Notifications to the Depositor. If requested, NCIMB will telephone or telex the date of deposit and the accession number after the microorganism has been received, but before the official receipt is issued. However, the depositor is told that such information is provisional, pending the outcome of the viability test. NCIMB will similarly communicate the result of the viability test before the viability statement is issued.

Supply of Information to a Patent Agent. NCIMB routinely asks the depositor for the name and address of his patent agent and, if requested, will supply copies of the receipt, viability statement and any other information to both the depositor and his patent agent.

(iii) Converting a Previous Deposit

Deposits made outside the provisions of the Budapest Treaty may be converted by the original depositor to Budapest Treaty deposits, whether or not they were originally made for patent purposes. However, in the case of deposits previously made for scientific purposes and which are already generally available from NCIMB, the depositor is requested to authorize NCIMB to continue to make them so available and to waive his right to be notified of the release of samples. If the depositor is unwilling to accede to this request, he must make another deposit of the same organism under the Budapest Treaty. These constraints do not apply to deposits previously made for patent purposes or to deposits made confidentially for safekeeping. Any deposit previously made free of charge is subject, on conversion, to the storage fee normally levied for Budapest Treaty deposits. With the exceptions noted above, the administrative requirements for conversion are the same as those to be met in respect of an original deposit made under the Treaty.

(iv) Making a New Deposit

The depositor is required to complete model form BP/2 when making a new deposit, and to supply copies of the relevant documents required by Rule 6.2. The receipt and viability statement for a new deposit are issued on mandatory “international forms” BP/5 and BP/9.

2. Furnishing of Samples

(a) Requests for Samples

NCIMB advises third parties of the correct procedures to follow in order to make a valid request. In the case of requests requiring proof of entitlement, NCIMB will provide requesting parties with copies of model request form BP/12 and/or request forms used by individual industrial property offices (where it has been supplied with such forms).

Notwithstanding any entitlement of third parties to receive samples under patent regulations, samples of plant pathogens or seeds requiring a permit to be worked with are not

released to requesting parties in the United Kingdom until NCIMB has confirmed that such parties have obtained the necessary permit. Also, samples of all microorganisms are delivered only to recognized microbiological laboratories and not to private addresses. When responding to requests from abroad, NCIMB assumes that the requesting party has met the import requirements of his own country.

All samples of bacteria furnished by NCIMB are from batches of its own preparations; samples of bacteriophages may be from its own preparations or from material supplied by the depositor; samples of plasmids and seeds are from material supplied by the depositor.

(b) Notification of the Depositor

Depositors are notified on model form BP/14 when samples of their microorganism have been furnished to third parties.

(c) Cataloguing of Budapest Treaty Deposits

NCIMB lists Budapest Treaty deposits in its published catalog only with the specific written authorization of the depositor.

3. Schedule of Fees

	Pounds Sterling
(a) <u>Storage of the microorganism</u>	495
(b) <u>Issuance</u>	75
(c) <u>Furnishing of a sample in accordance with Rule 11.2 and 11.3</u>	50 (plus carriage)

Fees are payable to NCIMB Ltd. Where applicable, fees are subject to Value Added Tax at the current rate.

Where statutory provisions require NCIMB to obtain a license or certificate prior to accepting a deposit of seeds, the actual cost of obtaining any such license or certificate will be charged to the depositor.

4. Guidance for Depositors

NCIMB publishes a leaflet containing guidance notes for prospective depositors.

GB – UNITED KINGDOM

NATIONAL COLLECTION OF TYPE CULTURES (NCTC)

Central Public Health Laboratory
61 Colindale Avenue
LONDON NW9 5HT
United Kingdom

Telephone: (081) 200 4400
Telex: 8953942 DEFEND G
Internet home page: <http://www.phis.co.uk/services/nctc/>

(See *Industrial Property*, 1982, pp. 219 and 220; *Industrial Property & Copyright*, 1996, p. 117.)

1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

Bacteria that can be preserved without significant change to their properties by freeze-drying and which are pathogenic to man and/or animals. Bacteria submitted for deposit must not require containment facilities greater than those appropriate to ACDP Hazard Group 3 as defined by the UK Advisory Committee on Dangerous Pathogens (ACDP), 1984, "Categorisation of Pathogens according to Hazard and Categories of Containment" (HMSO, London, ISBN 011 883761 3).

(b) Technical Requirements and Procedures

(i) Form and Quantity

Cultures of bacteria are accepted by the NCTC either lyophilized or in agar slabs. The depositor is required to provide only one culture when making his deposit.

(ii) Time Required for Viability Testing

The average length of time required for testing the viability of bacteria accepted by the NCTC is four days, but depositors should realize that in some cases viability testing may take as long as 14 days.

(iii) Depositor Checks and Renewal of Stocks

The NCTC prepares its own lyophilized batches of bacteria at the time of deposit by subculturing material supplied by the depositor. New batches are prepared from these as necessary thereafter for the renewal of diminishing stocks. The depositor is required to test

for authenticity samples of the first batch of his microorganism (but not subsequent batches) prepared by the NCTC.

The NCTC does not store material originally supplied by the depositor.

(c) Administrative Requirements and Procedures

(i) General

Language. The official language of the NCTC is English. Communications in any other language are not accepted.

Contract. The NCTC application form, which the depositor is required to complete, constitutes a contract by which he is bound:

- to provide all necessary information requested by the NCTC;
- to replace the microorganism at his expense if the NCTC is no longer able to furnish samples of it;
- to pay all necessary fees;
- to indemnify the Public Health Laboratory Service Board or the NCTC against any claims which may be brought against them as a consequence of the release of samples, unless such claims result from negligence on the part of the NCTC;
- not to withdraw his deposit during the required storage period;
- to authorize the NCTC to furnish samples according to the applicable patent requirements.

A supplement to the NCTC application form requires the depositor to state whether he is acting on his own behalf or on behalf of the organization employing him.

Import and/or Quarantine Regulations. Animal pathogenic bacteria being sent from overseas are subject to import regulations (Importation of Animal Pathogens Order 1980; Statutory Instrument 1980 No. 1212). The Central Public Health Laboratory, of which the NCTC is part, has a general license to cover the import of animal pathogens, but the depositor is required to give the NCTC his name and address and the scientific name of the organism to be deposited. Further information about the import of animal pathogens may be obtained from the Import Section (Animal Pathogens), Ministry of Agriculture, Fisheries and Food, Hood Rise South, Tolworth, Surbiton, Surrey KT6 7NF, United Kingdom.

The kinds of microorganisms accepted for deposit by the NCTC are not subject to quarantine regulations.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. As well as the NCTC application form referred to in (i), above, depositors are required to complete both the NCTC accession form for Budapest Treaty deposits and the NCTC standard accession form. The NCTC does not require a special form to be completed in the event of a later indication or amendment of the scientific description and/or proposed taxonomic designation or for a request for attestation that the NCTC has received such information.

Official Notifications to the Depositor. The receipt and viability statement are issued on mandatory “international forms” BP/4 and BP/9, respectively. Letters, rather than standard forms, are used for all other official notifications.

Unofficial Notifications to the Depositor. The NCTC does not telephone or telex the date of deposit, accession number or result of the viability test in advance of the relevant official notifications.

Supply of Information to a Patent Agent. The NCTC does not routinely ask the depositor for the name and address of his patent agent. However, if requested, it will send copies of the receipt and viability statement to both the depositor and his patent agent.

(iii) Converting a Previous Deposit

The NCTC does not accept deposits for patent purposes outside the provisions of the Budapest Treaty, nor does it permit the conversion of deposits previously made for scientific purposes to Budapest Treaty deposits. In the latter case, the NCTC requires the same organism to be redeposited under the terms of the Treaty. Thus Rule 6.4(d) does not apply.

(iv) Making a New Deposit

The depositor is required to complete model form BP/2 when making a new deposit, and to send copies of the relevant documents (Rule 6.2).

2. Furnishing of Samples

(a) Requests for Samples

The NCTC advises third parties of the correct procedures to follow in order to make a valid request. In the case of requests requiring proof of entitlement, the NCTC will provide requesting parties with copies of model request form BP/12 and/or request forms used by individual industrial property offices (where it has been supplied with such forms).

Notwithstanding any entitlement to receive samples under patent regulations, in the case of potentially dangerous microorganisms of ACDP Hazard Group 3, the requesting party must previously have been authorized by his head of department as being competent to request such organisms. This authorization, which must be made out on a special NCTC form, is required

only once in respect of any one individual. When responding to requests from overseas, the NCTC assumes that the requesting party has met the import requirements of his own country.

The NCTC reserves the right to withhold the supply of samples to parties having outstanding debts in respect of any previous transactions with the NCTC until such debts have been settled.

All samples furnished by the NCTC are from batches of its own preparations.

(b) Notification of the Depositor

Depositors are notified by letter when samples of their microorganism have been furnished to third parties.

(c) Cataloguing of Budapest Treaty Deposits

The NCTC does not list deposits made under the Budapest Treaty in its published catalog.

3. Schedule of Fees

	Pounds Sterling
(a) <u>Storage</u> (per strain)	450
(b) <u>Issuance of viability statement</u> (per statement)	60
(c) <u>Furnishing of samples</u> (per ampoule, plus cost of carriage)	45
(d) <u>Thirty year declaration for already deposited collection strains</u> (per declaration)	50

Fees paid within the United Kingdom are subject to Value Added Tax at the current rate.

Item (a) refers to Hazard Group 2 (fees for Hazard Group 3 increase by 50%). For items (c) and (d) the fees are subject to Value Added Tax at the current rate where appropriate.

4. Guidance for Depositors

The NCTC makes available to prospective depositors copies of Industrial Property, 1982, pp. 219 and 220, which contains information furnished by the United Kingdom Government in respect of the NCTC immediately prior to its acquisition of IDA status.

GB – UNITED KINGDOM

NATIONAL COLLECTION OF YEAST CULTURES (NCYC)

AFRC Institute of Food Research
Norwich Laboratory
Colney Lane
NORWICH NR4 7UA
United Kingdom

Telephone: (0603) 56122
Telex: 975453 G
E-mail: DIALCOM CDT 0005
Internet home page: <http://www.ifrn.bbsrc.ac.uk/ncyc/>

(See *Industrial Property*, 1982, pp. 24 and 26; 1988, p. 265; 1990, p. 25.)

1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

Yeasts, other than known pathogens, that can be preserved without significant change to their properties by freeze-drying or, exceptionally, in active culture. Deposits containing recombinant DNA molecules must not require containment levels higher than those associated with good microbiological practice as defined by the UK Genetic Manipulation Advisory Group, Guidance Note 15 (Health and Safety Executive, Baynards House, 1 Chepstow Place, London W2 4TF, United Kingdom).

(b) Technical Requirements and Procedures

(i) Form and Quantity

Cultures of yeasts are accepted by the NCYC either lyophilized or on agar slopes. The minimum number of replicates that must be provided by the depositor when making his deposit is two for lyophilized preparations and two for agar slope cultures.

(ii) Time Required for Viability Testing

The average length of time required for testing the viability of yeasts accepted by the NCYC is five days, but depositors should be aware that in some cases viability testing may take as long as 14 days.

(iii) Depositor Checks and Renewal of Stocks

The NCYC prepares its own lyophilized batches of the microorganism at the time of deposit, by subculturing material supplied by the depositor. New batches are prepared from

these whenever necessary thereafter for the renewal of diminishing stocks. The depositor is required to test for authenticity samples from all batches of his microorganism prepared by the NCYC.

The NCYC stores material originally supplied by the depositor only until its own procedures have been completed.

(c) Administrative Requirements and Procedures

(i) General

Language. The official language of the NCYC is English. Communications in any other language are not accepted.

Contract. The NCYC application form, which the depositor is required to complete, constitutes a contract by which he is bound:

- to provide all necessary information requested by the NCYC;
- to replace the microorganism at his expense if the NCYC is no longer able to furnish samples of it;
- to pay all necessary fees;
- to indemnify the NCYC against any claims which may be brought against it as a consequence of the release of samples, unless such claims result from negligence on the part of the NCYC;
- not to withdraw his deposit during the required storage period;
- to authorize the NCYC to furnish samples according to the applicable patent requirements.

Import and/or Quarantine Regulations. The kinds of microorganisms accepted by the NCYC are not subject to import or quarantine regulations.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. As well as the NCYC application form referred to in (i), above, depositors are required to complete the NCYC accession form for patent deposits. The NCYC does not require a special form to be completed in the event of a later indication or amendment of the scientific description and/or proposed taxonomic designation, or for a request for attestation that the NCYC has received such information.

Official Notifications to the Depositor. The receipt and viability statement are issued on mandatory “international forms” BP/4 and BP/9, respectively. A standard form is used for

notifying the depositor of refusal to accept a microorganism for deposit, but standard forms are not used for other official notifications.

Unofficial Notifications to the Depositor. If requested, the NCYC will telephone or telex the date of deposit and accession number after the microorganism has been received, but before the official receipt is issued. The NCYC will similarly communicate the result of the viability test before the viability statement is issued.

Supply of Information to a Patent Agent. The NCYC does not routinely ask the depositor for the name and address of his patent agent. However, if requested, the NCYC will supply copies of the receipt and viability statement to either the depositor or his patent agent, but not to both.

(iii) Converting a Previous Deposit

Deposits made outside the provisions of the Budapest Treaty may be converted by the original depositor to Budapest Treaty deposits, whether or not they were originally deposited for patent purposes. However, any deposits previously made free of charge are subject on conversion to the storage fees normally levied for Budapest Treaty deposits. The administrative requirements for conversion are the same as those to be met in respect of an original deposit made under the Treaty.

(iv) Making a New Deposit

The NCYC does not require the depositor to complete a standard form when making a new deposit, but he must supply copies of the relevant documents and declarations required by Rule 6.2. The receipt and viability statement for a new deposit are issued on mandatory “international forms” BP/5 and BP/9, respectively.

2. Furnishing of Samples

(a) Requests for Samples

The NCYC advises third parties of the correct procedures to follow in order to make a valid request. In the case of requests requiring proof of entitlement, the NCYC will provide requesting parties with copies of model request form BP/12 and/or request forms used by individual industrial property offices (where it has been supplied with such forms). When responding to requests from overseas, the NCYC assumes that the requesting party has met the import requirements of his own country.

All samples furnished by the NCYC are from batches of its own preparations.

(b) Notification of the Depositor

Depositors are notified by letter when samples of their microorganism have been furnished to third parties.

(c) Cataloguing of Budapest Treaty Deposits

The NCYC does not list Budapest Treaty deposits in its published catalog.

3. Schedule of Fees

	Pounds Sterling
(a) <u>Storage</u>	350
(b) <u>Issuance of viability statement</u>	50
(c) <u>Furnishing of samples</u>	30 (plus actual cost of carriage)

Fees paid within the United Kingdom are subject to Value Added Tax at the current rate.

4. Guidance for Depositors

The NCYC does not produce a standard letter or guidance notes for prospective depositors.

HU – HUNGARY

NATIONAL COLLECTION OF AGRICULTURAL AND INDUSTRIAL MICROORGANISMS (NCAIM)

Kertészeti és Élelmiszeripari Egyetem Mikrobiológiai és Biotechnológiai Tanszék
(Department of Microbiology and Biotechnology, University for Horticulture and the Food
Industry)
Somlói út 14-16
H-1118 BUDAPEST
Hungary

Telephone/Fax: (36 1) 372 6322
Internet home page: <http://ncaim.kee.hu/>

(See *Industrial Property*, 1986, pp. 203 and 432; 1993, p. 83; *Intellectual Property Laws and
Treaties*, 1999, p. 5.)

1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

Bacteria (including *Streptomyces*) except obligate human pathogenic species (e.g., *Corynebacterium diphtheriae*, *Mycobacterium leprae*, *Yersinia pestis*, etc.); fungi, including yeasts and moulds, except some pathogens (*Blastomyces*, *Coccidioides*, *Histoplasma*, etc.) and certain basidiomycetous and plant pathogenic fungi which cannot be preserved reliably. At present, the NCAIM is not ready to accept viruses, bacteriophages, rickettsiae, algae, protozoa, cell lines and hybridomas. Users will be notified when acceptance of such microorganisms becomes possible.

In general, the NCAIM is willing to accept strains of agriculturally and industrially important bacteria and fungi whose cultivation and preservation do not call for special conditions and which do not involve any health or other hazard to the environment.

(b) Technical Requirements and Procedures

(i) Form and Quantity

The NCAIM accepts microorganisms for deposit as either lyophilized preparations or active cultures. The minimum number of replicates that the depositor must supply when making his deposit is 25 for lyophilized preparations or three for active cultures.

(ii) Time Required for Viability Testing

The average length of time required for testing the viability of microorganisms accepted by the NCAIM is seven days, but depositors should realize that in some cases viability testing may take as long as 14 days.

(iii) Depositor Checks and Renewal of Stocks

Where the microorganism is deposited in active culture, the NCAIM prepares its own batches by subculturing the material supplied by the depositor. The depositor is required to check for authenticity samples of all such batches. The NCAIM does not prepare its own batches of microorganisms that have been supplied as lyophilized preparations by the depositor.

In all cases, the NCAIM renews diminishing stocks of deposited microorganisms by asking the depositor to make a new deposit.

Whichever method is used for preparing batches of samples for distribution, the NCAIM nevertheless stores a portion of the original material supplied by the depositor.

(c) Administrative Requirements and Procedures

(i) General

Language. The official language of the NCAIM is Hungarian. Communications are also accepted in English, French, German and Russian.

Contract. The NCAIM does not enter into a written contract with the depositor defining the liabilities of either party. However, by signing the NCAIM deposit form the depositor surrenders any right to withdraw his deposit during the required storage period.

Import and/or Quarantine Regulations. The kinds of microorganisms accepted by the NCAIM are not subject to import or quarantine regulations.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. The depositor is required to complete model form BP/1, which is used by the NCAIM as its accession form for Budapest Treaty deposits. In the event of later indication or amendment of the scientific description and/or proposed taxonomic designation, and a request for attestation that the NCAIM has received such information, the depositor must complete model form BP/7.

Official Notifications to the Depositor. The receipt and viability statement are issued on mandatory “international forms” BP/4 and BP/9, respectively. Attestation of receipt of a later indication or amendment of the scientific description and/or proposed taxonomic designation is issued on model form BP/8. Notification of furnishing of a sample to a third

party is issued on form BP/14. The NCAIM uses its own standard letters for other official notifications.

Unofficial Notifications to the Depositor. If requested, the NCAIM will telephone or telex the date of deposit and accession number after the microorganism has been received, but before the official receipt is issued. The NCAIM will similarly communicate the result of the viability test before the viability statement is issued.

Supply of Information to a Patent Agent. The NCAIM does not routinely ask the depositor for the name and address of his patent agent. However, if requested, the NCAIM will send copies of the receipt and viability statement to both the depositor and his patent agent.

(iii) Converting a Previous Deposit

Deposits made outside the provisions of the Budapest Treaty may be converted by the original depositor to Budapest Treaty deposits, whether or not they were originally deposited for patent purposes. All conversions are subject to the storage fee normally levied for Budapest Treaty deposits, regardless of whether any fee had previously been paid in respect of those deposits.

The administrative requirements for conversion are the same as those to be met in respect of an original deposit made under the Treaty.

(iv) Making a New Deposit

The depositor is required to complete model form BP/2 when making a new deposit and to supply copies of the relevant documents required by Rule 6.2. The receipt and viability statement are issued on mandatory “international forms” BP/5 and BP/9, respectively.

2. Furnishing of Samples

(a) Requests for Samples

The NCAIM advises third parties of the correct procedures to follow in order to make a valid request. In the case of requests requiring proof of entitlement, the NCAIM will provide requesting parties with copies of model request form BP/12 and/or request forms used by individual industrial property offices (where it has been supplied with such forms). Notwithstanding any entitlement to receive samples under patent regulations, a requesting party must show, by a business letterhead or requisition form or in some other way, that he is trained in microbiology and has access to a properly equipped laboratory. When responding to requests from overseas, the NCAIM assumes the requesting party has met the import requirements of his own country.

Samples furnished by the NCAIM may be from preparations supplied by the depositor, or from its own preparations, depending on the form in which the microorganism was deposited.

(b) Notification of the Depositor

Depositors are notified on model form BP/14 when samples of their microorganism have been furnished to third parties.

(c) Cataloguing of Budapest Treaty Deposits

The NCAIM does not list Budapest Treaty deposits in its published catalog.

3. Schedule of Fees

	Forint
(a) <u>Storage</u>	108,000
(b) <u>Issuance of a receipt in attestation of the deposit (except for the receipt issued free of charge in the case of original or new deposits) if information is requested</u>	6,000
(c) <u>For a viability test and for the issuance of a viability statement</u>	15,000
(d) <u>For the furnishing of samples on request made after publication of the patent application</u>	25,000

4. Guidance for Depositors

The NCAIM does not at present produce a standard letter or guidance notes for prospective depositors.

IT – ITALY

ADVANCED BIOTECHNOLOGY CENTER (ABC)

Biotechnology Department
Largo Rossana Benzi, 10
16132 GENOA
Italy

Telephone: (010) 5737-474
Telefax: (010) 5737-295
Internet home page: <http://www.biotech.ist.unige.it/>

(See *Industrial Property and Copyright*, 1996, p.80.)

1. Requirements for deposit

(a) Kinds of Microorganisms that may be Deposited

The ABC accepts for deposit human and animal cell lines and hybridomas, provided that they can be stored in liquid nitrogen vapors, without any significant loss of viability. The genetically modified cell lines are also accepted if they belong to group 1 of Genetically modified microorganisms. As to dangerous pathogens, no deposits are accepted of cell lines and hybridomas beyond Category of Containment 2¹.

However, the ABC reserves the right to refuse any material whose manipulation represents an unacceptable risk or is technically difficult. The ABC requests that a form on the cell line/hybridoma characteristics be filled in upon deposit.

(b) Technical Requirements and Procedures

(i) Form and Quantity

Cell lines and hybridomas. At least 12 frozen ampoules must be provided for each cell line deposited, containing not less than 2×10^6 cells per ampoule. The ampoules must be sent with a quantity of dry ice sufficient to remain frozen during the transport. If the package is found inadequate, the culture will not be accepted.

¹ Italian Decree Law 91/93, "Application of Directive 90/219/EC, concerning the confined use of genetically modified microorganisms;" Italian Decree Law 626/94, "Application of Directives 89/391/EC, 89/654/EC, 89/655/EC, 89/656/EC, 90/269/EC, 90/270/EC, 90/394/EC, 90/679/EC, concerning the improvement of security and health of workers in the workplace."

(ii) Time Required for Viability Testing

The average delay needed for the control of viability of the cell lines and hybridomas is of 10-14 days (the depositors should be aware that in some cases the control may take longer).

(iii) Depositor Checks and Renewal of Stocks

In general, the ABC does not prepare its stocks of cell lines/hybridomas, and when the stocks are exhausted because of the delivery of samples, it requests the depositor to make a new deposit. In some special cases, by an agreement with the depositor, the ABC can prepare its stocks of the material, asking the depositor to verify the authenticity and quality of the material.

(c) Administrative Requirements and Procedures

(i) General

Language. The official language of the ABC is Italian. Deposits are also accepted in English and French.

Contract. The depositor must fill in a form in which he declares his agreement on the following:

- to deposit the material only in the required form and quantity;
- to indicate the characteristics of the cell line/hybridoma relating to danger and pathogenicity;
- to pay all required fees, including the postal expenses for the shipment(s) of the cell line/hybridoma to the ABC;
- to comply with the requirements of the Budapest Treaty;
- to comply with the requirements of the ABC concerning the deposit of microorganisms.

Import and/or Quarantine Regulations. The kind of material accepted for deposit by ABC is not required to follow any particular rule.

(ii) Making the Original Deposit

Requirements to be Met by the Depositor. The depositor is required to fill in a deposit form which includes a declaration on the pathogenicity of the cell line/hybridoma.

Forty eight hours before shipping the material, the depositor must inform the ABC about the number of samples sent for deposit, the means of transport chosen and the expected time of arrival. If the material is sent by air, the ABC must be informed of the flight number, destination, number of bill and carrier.

Official Notifications to the Depositor. The receipt and the viability statement are issued on mandatory “international forms” BP/4 and BP/9.

Unofficial Notifications to the Depositor. If requested, the ABC will communicate by telephone the date of deposit and the accession number of the cell line/hybridoma, before the official receipt is issued.

Supply of Information to a Patent Agent. If requested, the ABC will send a copy of the viability statement to the patent agent.

(iii) Converting a Previous Deposit

Deposits made outside the Budapest Treaty can be converted by the original depositor to deposits under the Budapest Treaty. In this case, the fees normally payable under the Budapest Treaty are due. The other requirements are the same as for an original deposit.

(iv) Making a New Deposit

When making a new deposit, the depositor must fill in a deposit form which includes a declaration on the pathogenicity of the cell line/hybridoma, and the depositor must send a copy of the documents and of the declaration indicated in Rule 6.2. As to the shipment, the depositor must follow the technical requirements and procedures described in point 1(b) above.

2. Furnishing of Samples

(a) Requests for Samples

The ABC does not inform the requesting parties about the procedure to be followed for the request, and does not provide the forms of request which can be obtained from the relevant Patent Offices.

The ABC assumes that the requesting parties have satisfied all the national requirements concerning importation.

(b) Notification to the Depositor

When ABC delivers samples of the deposited microorganisms to third parties, it notifies the depositor by letter.

(c) Cataloguing of Budapest Treaty Deposits

The ABC does not include the deposits made under the Budapest Treaty in its catalogs.

3. Schedule of Fees

	Italian lire
Cell lines and hybridomas	
(a) <u>Storage</u>	2.000.000
(b) <u>Issue of viability statement</u>	100.000
(c) <u>Furnishing of samples</u>	250.000
(d) <u>Requesting authorizations from competent authorities</u>	200.000

The fees, with the addition of the Value Added Tax, where relevant, are payable to the “Consorzio per la gestione del Centro di Biotecnologie Avanzate” (Management Consortium of the Advanced Biotechnology Center).

4. Guidance for Depositors

The forms of the ABC for the deposit contain the recommendations for the depositors.

IT – ITALY

COLLECTION OF INDUSTRIAL YEAST'S DBVPG

Department of Plant Biology
University of Perugia
Borgo 20 Giugno, 74
06122 Perugia
Italy

Telephone: (075) 5856483
Telefax: (075) 585 6470
E-mail: martinal@egeo.unipg.it

(See *Industrial Property and Copyright*, 1997, p. 45.)

1. Requirements for Deposit

(a) Kinds of Microorganisms that may be Deposited

Yeasts and yeast-like fungi, with the exception of those having properties that may be dangerous to human health.

(b) Technical Requirements and Procedures

(i) Form and quantity

Samples must be sent in test tubes in liquid or gel form or in freeze-dried ampoules in rigid-sided containers. Frozen or deep frozen cultures must be shipped in containers of expanded polystyrene containing a quantity of dry ice sufficient to guarantee 48 hours autonomy at room temperature. The cells of the strain dispatched must be in pure culture and provide a high level of viability. In the presence of contamination by bacteria, molds, other yeasts and acarina, the dispatched culture is immediately sterilized.

(ii) Time Required for Viability Testing

The average length of time required for testing the viability of deposited cultures is 20 days.

(iii) Depositor Checks and Renewal of Stocks

The DBVPG prepares its own batches of the microorganism at the time of deposit by subculturing the material supplied by the depositor. New batches are prepared from these as necessary thereafter for the renewal of diminishing stocks. The DBVPG always stores a portion of the original material supplied by the depositor.

(c) Administrative Requirement and Procedures

(i) General

Language. The official language of the DBVPG is Italian. Deposits are also accepted in English and French.

Contract. The depositor must fill in a form in which he/she declares his agreement on the following:

- to deposit the material only in the required form and quantity;
- to indicate the characteristics of the yeast culture related to danger or pathogenicity;
- to pay all the required fees;
- to comply with the requirements of the Budapest Treaty;
- to comply with the requirements of the DBVPG concerning the deposit of yeasts.

(ii) Import and/or Quarantine Regulations

The material accepted for deposit by DBVPG is not required to follow any particular rule.

(iii) Making the Original Deposit

Requirements to be Met by the Depositor. The depositor is required to fill in a deposit form which includes a declaration on the pathogenicity of the yeast culture. Forty-eight hours before shipping the material, the depositor must inform the DBVPG about the number of samples sent for deposit, the means of transportation and the expected time of arrival; in case of air shipment, the DBVPG must be informed of the flight number, destination, number of bill and carrier.

Official Notification to the Depositor. The receipt and the viability statement are issued on mandatory “international forms” BP/4 and BP/9.

Unofficial Notification to the Depositor. If requested, the DBVPG will communicate by telephone the date of deposit and the accession number of the yeast culture, before the official receipt is issued.

Supply of Information to a Patent Agent. If requested, the DBVPG will send a copy of the viability statement to the patent agent.

(vi) Converting a Previous Deposit

Deposits made outside the Budapest Treaty can be converted by the original depositor to deposits under the Budapest Treaty. In this case, the fees normally payable under the Budapest Treaty are due. The requirements are the same as for an original deposit.

(v) Making a New Deposit

When making a new deposit, the depositor must fill in a deposit form which includes a declaration on the pathogenicity of the yeast culture, and the depositor must send a copy of the documents of the declaration indicated in Rule 6.2. As to the shipment, the depositor must follow the technical requirements and procedures described in point 1(b).

2. Furnishing of Samples

(a) Requests for Samples

The DBVPG does not inform the requesting parties about the procedure to be followed for the request, and does not provide the forms of request which can be obtained from the relevant Patent Office.

The DBVPG assumes that the requesting parties have satisfied all the national requirements concerning importation.

(b) Notification to the Depositor

When the DBVPG delivers samples of the deposited microorganism to third parties, it notifies the depositor by letter.

(c) Cataloguing of Budapest Treaty Deposits

The DBVPG does not include the deposits made under the Budapest Treaty in its catalogs.

3. Schedule of Fees

	Italian lire
(a) <u>Storage</u> (one strain)	1.000.000
(b) <u>Issue of viability statement</u>	100.000
(c) <u>Furnishing of samples</u>	200.000
(d) <u>Requesting authorizations from competent authorities</u>	40.000

The fees, with the addition of the Value Added Tax, where relevant, are payable to the “Dipartimento di Biologia Vegetale dell'Università di Perugia” (Department of Plant Biology of the University of Perugia).

4. Guidance for the Depositors

The forms of the DBVPG for the deposit contain the recommendations for the depositor.

JP – JAPAN

NATIONAL INSTITUTE OF BIOSCIENCE AND HUMAN-TECHNOLOGY (NIBH)

Agency of Industrial Science and Technology
Ministry of International Trade and Industry
1-3, Higashi, Tsukuba-shi
IBARAKI 305
Japan

Telephone: (081298) 61-6001
Facsimile: (081298) 61-6009
Internet home page: <http://www.nibh.go.jp>

(See *Industrial Property*, 1981, pp. 120 and 122; 1984, p. 114; 1987, p. 331; 1988, p. 139; 1989, pp. 51 and 172; 1993, pp. 27 and 83; 1994, p. 67; *Industrial Property and Copyright*, 1997, p. 89; *Intellectual Property Laws and Treaties*, 2000, p. 5.)

1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

Fungi, yeasts, bacteria, actinomycetes, plasmids (naked), animal cell cultures, embryos, protozoa, plant cell cultures, seeds and algae, EXCEPT:

- microorganisms having properties which are or may be dangerous to human health or the environment; or
- microorganisms which require the physical containment level P₃ or P₄ for experiments, as described in the 1986 “Prime Minister’s Guidelines for Recombinant DNA Experiments.”

(b) Technical Requirements and Procedures

(i) Form and Quantity

Microorganisms should be submitted for deposit as lyophilized preparations or as agar stab or slant cultures. The minimum number of replicates that must be supplied by the depositor when making his deposit, and the form in which they must be submitted, are as follows:

fungi, yeasts, bacteria and actinomycetes	5 lyophilized
animal cell cultures	20 frozen
plant cell cultures	5 as tissue cultures on a solid medium

(ii) Time Required for Viability Testing

The average length of time required for testing the viability of the various kinds of microorganisms accepted by the NIBH is 20 days, but depositors should realize that in some cases viability testing may take as long as 60 days.

(iii) Depositor Checks and Renewal of Stocks

The NIBH prepares its own batches of the microorganism at the time of deposit by subculturing material supplied by the depositor. New batches are prepared from these as necessary thereafter for the renewal of diminishing stocks. For animal cell cultures, NIBH uses replicates (see above) supplied by the depositor at the time of deposit.

Despite the methods for preparing batches of samples for distribution, the NIBH nevertheless stores a portion of the original material supplied by the depositor.

(c) Administrative Requirements and Procedures

(i) General

Language. The official language of the NIBH is Japanese. However, the power of attorney and other attached documents can be in another language, but must be accompanied by a Japanese translation. Requests for samples may be in Japanese, English or French.

Contract. The NIBH does not enter into a written contract with the depositor defining the liabilities of either party but, by signing the NIBH deposit form, the depositor surrenders any right to withdraw his microorganism during the required storage period.

Import and/or Quarantine Regulations. Certain plant and animal pathogens are subject to import and/or quarantine regulations. The NIBH advises prospective depositors of such microorganisms of the procedures that must be followed to obtain the necessary permits. On average, obtaining a permit takes about three weeks. Further information can be obtained from the Yokohama Plant Protection Station, Ministry of Agriculture, Forestry and Fisheries, 5-57 Kitanankadori, Naka-ku, Yokohama, Japan, and from the Animal Quarantine Service, Ministry of Agriculture, Forestry and Fisheries, 11-1 Hara-machi, Isogo-ku, Yokohama, Japan.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. Depositors are required to complete the equivalent of model form BP/1, which is used by the NIBH as its accession form for Budapest Treaty deposits. In the event of later indication or amendment of the scientific description and/or proposed taxonomic designation, and a request for attestation that the NIBH has received such information, the depositor must complete the equivalent of model form BP/7.

Official Notifications to the Depositor. The receipt and viability statement are issued on mandatory “international forms” BP/4 and BP/9, respectively. Attestation of receipt of a later indication or amendment of the scientific description and/or proposed taxonomic designation is issued on the equivalent of model form BP/8. Notification of release of a sample to a third party is issued on form BP/14. The NIBH has its own standard forms for other official notifications.

Unofficial Notifications to the Depositor. If requested, the NIBH will telephone or telex the date of deposit and accession number after the microorganism has been received, but before the official receipt is issued. The NIBH will similarly communicate the result of the viability test before the viability statement is issued.

Supply of Information to a Patent Agent. The NIBH does not routinely ask the depositor for the name and address of his patent agent. The NIBH will send copies of the receipt and viability statement either to the depositor or to his agent if requested, but not to both.

(iii) Converting a Previous Deposit

Deposits made outside the provisions of the Budapest Treaty may be converted by the original depositor to Budapest Treaty deposits only if they were originally made for patent purposes. The administrative requirements for conversion are similar to those to be met in respect of an original deposit made under the Treaty, except that the depositor is also required to supply a copy of the receipt of the previous deposit. Conversions are subject to the normal storage fee levied for Budapest Treaty deposits in cases where any fee was previously charged in respect of their deposit for patent purposes outside the provisions of the Treaty.

(iv) Making a New Deposit

The depositor is required to complete model form BP/2 when making a new deposit and to supply copies of the relevant documents required by Rule 6.2. The receipt and viability statement are issued on mandatory “international forms” BP/5 and BP/9, respectively.

2. Furnishing of Samples

(a) Requests for Samples

The NIBH advises third parties of the correct procedures to follow in order to make a valid request. In the case of requests requiring proof of entitlement, the NIBH will provide requesting parties with copies of model request form BP/12 and/or request forms used by individual industrial property offices (where it has been supplied with such forms).

The NIBH furnishes samples in the belief that it is the responsibility of the requesting party to ensure that he complies with any relevant health and safety requirements. When responding to requests from overseas, the NIBH assumes that the requesting party has met the import requirements of his own country.

All samples of microorganisms furnished by the NIBH are from batches of its own preparations of the microorganism, with the exception of animal cell cultures (see above).

(b) Notification of the Depositor

Depositors are notified on model form BP/14 when samples of their microorganism have been furnished to third parties.

(c) Cataloguing of Budapest Treaty Deposits

The NIBH does not list Budapest Treaty deposits in its published catalog.

3. Schedule of Fees

	Yen
(a) <u>Storage</u>	
– original deposits	220,000
– new deposits	16,000
(b) <u>Attestation referred to in Rule 8.2</u>	2,000
(c) <u>Issuance of a viability statement</u>	
– if the viability test is requested	8,900
– on other cases	2,000
(d) <u>Furnishing of a sample</u>	10,000 ¹
(e) <u>Communication of information under Rule 7.6</u>	2,000

¹ When furnishing a sample to a foreign institution:

– An additional 33,000 yen per package corresponding to the cost of a special container is payable for animal cell cultures;

– An additional 150 yen per package corresponding to the cost of a special container is payable for other microorganisms.

Fees are expressed net of Value Added Tax according to Japanese provisions currently in force.

4. Guidance for Depositors

The NIBH produces notes for the guidance of prospective depositors.

KR – REPUBLIC OF KOREA

KOREAN CULTURE CENTER OF MICROORGANISMS (KCCM)

361-221, Yurim B/D
Honje 1, Sudaemum
SEOUL, 120-091
Republic of Korea

Telephone: (8242) 392-0950
Telefax: (8242) 392-2859
Internet home page: <http://www.kccm.or.kr/>

(See *Industrial Property*, 1990, pp. 135 and 137, *Intellectual Property Laws and Treaties*, 1999, p. 70.)

1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

Bacteria, actinomycetes, fungi, yeasts, plasmids, bacteria containing plasmids, viruses, bacteriophages, except:

- hybridomas, plant tissue cultures, rickettsiae;
- microorganisms liable to require viability testing that the KCCM is technically not able to carry out;
- mixtures of undefined and/or unidentifiable microorganisms.

The KCCM reserves the right to refuse any microorganism for security reasons: specific risks to human beings, animals, plants and the environment. In cases where a microorganism cannot be lyophilized, the KCCM must be consulted in advance about the conditions for acceptance.

(b) Technical Requirements and Procedures

(i) Form and Quantity

Whenever possible, cultures submitted to the KCCM for deposit should be lyophilized. Viruses that cannot be lyophilized and bacteriophages should be frozen. All replicates of the microorganisms to be deposited should be from the same batch of lyophilized or frozen preparations.

Bacteriophage suspensions must contain at least 10^7 plaque forming units per ml.

The minimum number of replicates that must be submitted by the depositor is as follows:

bacteria, fungi, yeasts, actinomycetes	8
plasmids, bacteria containing plasmids, viruses, bacteriophages	25

(ii) Time Required for Viability Testing

The average length of time required for testing the viability of the microorganisms accepted by the KCCM is given below, but depositors should realize that in some cases it may take longer.

bacteria	7 days (or up to 14 days)
fungi, yeasts, actinomycetes	10 days (or up to 20 days)
plasmids, bacteria containing plasmids, viruses, bacteriophages	14 days (or up to 30 days)

(iii) Depositor Checks and Renewal of Stocks

The KCCM prepares its own batches in lyophilized or frozen form at the time of deposit by subculturing the microorganism supplied by the depositor. New batches are prepared from these as necessary thereafter for the renewal of diminishing stocks. The depositor is required to test for authenticity samples of all batches of his microorganisms prepared by the KCCM.

Whichever method is used for preparing batches of samples for distribution, the KCCM nevertheless stores a portion of the original material supplied by the depositor.

(c) Administrative Requirements and Procedures

(i) General

Language. The official language of the KCCM is Korean. However, communications in English are also accepted.

Contract. The KCCM does not enter into a written contract with the depositor defining the liabilities of either party. However, by signing the KCCM deposit form, the depositor surrenders any right to withdraw his microorganism during the required storage period.

Import and/or Quarantine Regulations. Overseas depositors must contact the KCCM in advance for advice about the shipping of their microorganisms. Certain pathogens are subject to import and/or quarantine regulations. The KCCM advises prospective depositors of such microorganisms of the procedures that must be followed to obtain the necessary permits.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. Depositors are required to complete the equivalent of model form BP/1, which is used by the KCCM as its accession form for Budapest Treaty deposits. In the event of a later indication or amendment of the scientific description and/or proposed taxonomic designation, and a request for attestation that the KCCM has received such information, the depositor must complete the equivalent of model form BP/7.

Official Notifications to the Depositor. The receipt and viability statement are issued on mandatory “international forms” BP/4 and BP/9, respectively. Attestation of receipt of a later indication or amendment of the scientific description and/or proposed taxonomic designation is issued on the equivalent of model form BP/8. Notification of furnishing of a sample to a third party is issued on form BP/14. The KCCM has its own standard forms for other official notifications.

Unofficial Notifications to the Depositor. If requested, the KCCM will telephone the date of deposit and accession number after the microorganism has been received, but before the official receipt is issued. The KCCM will similarly communicate the result of the viability test before the viability statement is issued.

Supply of Information to a Patent Agent. The KCCM does not routinely ask the depositor for the name and address of his patent agent. The KCCM will send copies of the receipt and viability statement either to the depositor or to his agent if requested, but not to both.

(iii) Converting a Previous Deposit

Deposits made outside the provisions of the Budapest Treaty may be converted by the original depositor to Budapest Treaty deposits only if they were originally made for patent purposes. The administrative requirements for conversion are similar to those to be met in respect of an original deposit made under the Treaty, except that the depositor is also required to supply a copy of the receipt for the previous deposit. All conversions are subject to the normal storage fee levied for Budapest Treaty deposits, regardless of whether any fees have been paid previously in respect of those deposits.

(iv) Making a New Deposit

The depositor is required to complete model form BP/2 when making a new deposit and to supply copies of the relevant documents required by Rule 6.2. The receipt and viability statement for a new deposit are issued on mandatory “international forms” BP/5 and BP/9, respectively.

2. Furnishing of Samples

(a) Requests for Samples

The KCCM advises third parties of the correct procedures to follow in order to make a valid request. In the case of requests requiring proof of entitlement, the KCCM will provide requesting parties with copies of model request form BP/12 and/or request forms used by individual industrial property offices (where it has been supplied with such forms).

The KCCM furnishes samples in the belief that it is the responsibility of the requesting party to ensure that he complies with any relevant health and safety requirements. When responding to requests from overseas, the KCCM assumes that the requesting party has met the import requirements of his own country.

All samples of microorganisms furnished by the KCCM are from batches of its own preparations of the microorganisms.

(b) Notification of the Depositor

Depositors are notified on model form BP/14 when samples of their microorganisms have been furnished to third parties.

(c) Cataloguing of Budapest Treaty Deposits

The KCCM does not list Budapest Treaty deposits in its published catalog.

3. Schedule of Fees

	Won
(a) <u>Storage</u>	
– original deposit	600,000
– new deposits	50,000
(b) <u>Issuance of viability statement</u>	
– if the depositor requiring a viability statement has also requested a viability test	20,000
– in other cases	10,000
(c) <u>Furnishing of samples</u>	50,000 (plus cost of transport)

	Won
(d) <u>Issuance of an attestation under Rule 8.2</u>	10,000
(e) <u>Communication of information under Rule 7.6</u>	10,000

4. Guidance for Depositors

The KCCM does not at present produce specific written notes for the guidance of prospective depositors, but is always ready to give advice by telephone or letter.

KR – REPUBLIC OF KOREA

KOREAN CELL LINE RESEARCH FOUNDATION (KCLRF)

Cancer Research Institute
Seoul National University College of Medicine
28 Yungon-dong, Chongno-gu
SEOUL 110-799
Republic of Korea

Telephone: 02-742-0020

Telefax: 02-742-0021

Internet home page: <http://cellbank.snu.ac.kr/home/default.asp>

(See *Industrial Property*, 1993, p. 212.)

1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

Cell lines (animal, plant and hybridomas).

At present KCLRF does not accept for deposit cell lines having properties which are or may be hazardous to health or the natural environment and cell lines which need special requirements for experiment.

(b) Technical Requirements and Procedures

(i) Form and Quantity

Whenever possible, cell lines submitted to KCLRF for deposit should be in the form of frozen and viable culture. All cell lines submitted to KCLRF for deposit should be free of contaminants.

The minimum number of replicates that must be provided by the depositor is as follows:

Cell lines in frozen form: 7

(ii) Time Required for Viability Testing

The average time required for testing the viability of cell lines accepted by KCLRF is as follows:

Cell lines (animal, plant and hybridomas): 14 days (or up to 28 days).

In some cases, the test may take longer.

(iii) Depositor Checks and Renewal of Stocks

KCLRF prepares its own batches in frozen form at the time of deposit by subculturing the microorganism supplied by the depositor. New batches are prepared from these as necessary thereafter. The depositor is required to check for authenticity samples of all batches prepared by KCLRF. Regardless of the methods for preparing the batches of samples for distribution, KCLRF stores a portion of the original material supplied by the depositor.

(c) Administrative Requirements and Procedures

(i) General

Language. Korean is the official language of KCLRF, but correspondence may be carried out also in English.

Contract. KCLRF does not enter into a written contract with the depositor defining the liabilities of either party. However, by signing the KCLRF deposit form, the depositor surrenders the right to withdraw his deposit during the required storage period.

Import and/or Quarantine Regulations. Overseas depositors must contact KCLRF in advance for advice about the shipping of their cell lines. Certain pathogens are subject to import and/or quarantine regulations. KCLRF advises prospective depositors concerning the procedures which must be followed to obtain the necessary permits.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. Depositors are required to complete the equivalent of model form BP/1, which is used by KCLRF as its accession form for Budapest Treaty deposits. In the event of a later indication or amendment of the scientific description and/or proposed taxonomic designation, the depositor must complete the equivalent of model form BP/7.

Official Notifications to the Depositor. The receipt and viability statement are issued on mandatory “international forms” BP/4 and BP/9, respectively. Attestation of receipt of a later indication or amendment of the scientific description and/or proposed taxonomic designation is issued on model form BP/8. Notification of furnishing of a sample to a third party is issued on model form BP/14. KCLRF has its own standard forms for other official notifications.

Unofficial Notifications to the Depositor. If requested, KCLRF will telephone the date of deposit and accession number after the microorganism has been received, but before the official receipt is issued. KCLRF will similarly communicate the result of the viability test before the viability statement is issued.

Supply of Information to a Patent Agent. KCLRf does not routinely ask the depositor for the name and address of his patent agent. KCLRf will send copies of the receipt and viability statement either to the depositor or to his agent if requested, but not to both.

(iii) Converting a Previous Deposit

Deposits made outside the provisions of the Budapest Treaty may be converted by the original depositor to Budapest Treaty deposits only if they were originally made for patent purposes. The administrative requirements for the conversion are similar to those to be met in respect of an original deposit made under the Treaty, except that the depositor is required to supply also a copy of the receipt for the previous deposit. All conversions are subject to payment of the normal storage fee levied on Budapest Treaty deposits, regardless of whether any fee had been paid previously in respect of those deposits.

(iv) Making a New Deposit

The depositor is required to complete model form BP/2 when making a new deposit and to supply copies of the relevant documents required by Rule 6.2. The receipt and viability statement for a new deposit are issued on mandatory “international forms” BP/5 and BP/9, respectively.

2. Furnishing of Samples

(a) Requests for Samples

KCLRf advises third parties of the correct procedures to follow in order to make a valid request. In the case of requests requiring proof of entitlement, KCLRf will provide the requesting parties with copies of a model request form BP/12 and/or request forms used by individual industrial property offices (where they have been supplied with such forms).

KCLRf furnishes samples on the basis that it is the responsibility of the requesting party to ensure that it complies with any relevant health and safety requirements. When responding to requests from overseas, KCLRf assumes that the requesting party has met the import requirements of its own country.

All samples of cell lines furnished by KCLRf are from batches of its own preparation.

(b) Notification of the Depositor

Depositors are notified in model form BP/14 when samples of their cell lines have been furnished to third parties.

(c) Cataloguing of Budapest Treaty Deposits

KCLRf does not list Budapest Treaty deposits in the catalog of its publications.

3. Schedules of Fees

	Won
(a) <u>Storage</u>	
– original deposits	600,000
– new deposit	50,000
(b) <u>Issue of viability statement</u>	
– if the depositor requiring a viability statement has also requested a viability test	20,000
– in other cases	10,000
(c) <u>Furnishing of samples</u>	50,000
(d) <u>Issuance of an attestation under Rule 8.2</u>	10,000
(e) <u>Communication of information under Rule 7.6</u>	10,000

4. Guidance for Depositors

KCLRF does not at present produce specific written notes for the guidance of prospective depositors, but is always ready to give advice by telephone or letter.

KR – REPUBLIC OF KOREA

KOREAN COLLECTION FOR TYPE CULTURES (KCTC)

#52, Oun-Dong
Yusong-Ku
305-333 TAEJON
Republic of Korea

Telephone: (8242) 829-4144
Telefax: (8242) 861-1759
Internet home page: <http://kctc.kribb.re.kr/>

(See *Industrial Property*, 1990, p. 135; 1991, p. 219; *Industrial Property and Copyright*, 1995, p. 298; *Intellectual Property Laws and Treaties*, 1998, p. 57; 1999, p. 120.)

1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

Algae, bacteria (including actinomycetes), bacteria containing plasmids, bacteriophages, cell cultures (including hybridoma lines), fungi (including yeasts), protozoa and animal, plant viruses, animal embryos and DNA (Eukaryotic DNA), EXCEPT:

- (a) microorganisms having properties which are or may be dangerous to health or the environment;
- (b) microorganisms which need the special containment required for experiments.

(b) Technical Requirements and Procedures

(i) Form and Quantity

Whenever possible, cultures submitted to the KCTC for deposit should be lyophilized. Viruses that cannot be lyophilized and bacteriophages should be frozen. All replicates of the microorganisms to be deposited should be from the same batch of lyophilized or frozen preparations.

The minimum number of replicates that must be submitted by the depositor is as follows:

actinomycetes, bacteria, fungi, yeasts, bacteria containing plasmid	10
plasmids, algae, protozoa, animal and plant cell lines, hybridomas, viruses, bacteriophages	25

(ii) Time Required for Viability Testing

The average length of time required for testing the viability of the microorganisms accepted by the KCTC is given below, but depositors should realize that in some cases it may take longer:

bacteria	7 days (or up to 14 days)
fungi, yeasts, actinomycetes, algae, protozoa	10 days (or up to 20 days)
plasmids, bacteria containing plasmids viruses, bacteriophages, animal and plant cell lines, hybridomas	14 days (or up to 30 days)

(iii) Depositor Checks and Renewal of Stocks

The KCTC prepares its own batches in lyophilized or frozen form at the time of deposit by subculturing the microorganism supplied by the depositor. New batches are prepared from these as necessary thereafter for the renewal of diminishing stocks. The depositor is required to test for authenticity samples of all batches of his microorganisms prepared by the KCTC.

Whichever method is used for preparing batches of samples for distribution, the KCTC nevertheless stores a portion of the original material supplied by the depositor.

(c) Administrative Requirements and Procedures

(i) General

Language. Korean is the official language of the KCTC. However, correspondence may also be carried out in English.

Contract. The KCTC does not enter into a written contract with the depositor defining the liabilities of either party. However, by signing the KCTC deposit form the depositor surrenders any right to withdraw his deposit during the required storage period.

Import and/or Quarantine Regulations. Overseas depositors must contact the KCTC in advance for advice about the shipping of their microorganisms. Certain pathogens are subject to import and/or quarantine regulations. The KCTC advises prospective depositors of such microorganisms of the procedures that must be followed to obtain the necessary permits.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. Depositors are required to complete the equivalent of model form BP/1, which is used by the KCTC as its accession form for Budapest Treaty deposits. In the event of a later indication or amendment of the scientific

description and/or proposed taxonomic designation, and a request for attestation that the KCTC has received such information, the depositor must complete the equivalent of model form BP/7.

Official Notifications to the Depositor. The receipt and viability statement are issued on mandatory “international forms” BP/4 and BP/9, respectively. Attestation of receipt of a later indication or amendment of the scientific description and/or proposed taxonomic designation is issued on the equivalent of model form BP/8. Notification of furnishing of a sample to a third party is issued on form BP/14. The KCTC has its own standard forms for other official notifications.

Unofficial Notifications to the Depositor. If requested, the KCTC will telephone the date of deposit and accession number after the microorganism has been received, but before the official receipt is issued. The KCTC will similarly communicate the result of the viability test before the viability statement is issued.

Supply of Information to a Patent Agent. The KCTC does not routinely ask the depositor for the name and address of his patent agent. The KCTC will send copies of the receipt and viability statement either to the depositor or to his agent if requested, but not to both.

(iii) Converting a Previous Deposit

Deposits made outside the provisions of the Budapest Treaty may be converted by the original depositor to Budapest Treaty deposits only if they were originally made for patent purposes. The administrative requirements for conversion are similar to those to be met in respect of an original deposit made under the Treaty, except that the depositor is also required to supply a copy of the receipt for the previous deposit. All conversions are subject to the normal storage fee levied for Budapest Treaty deposits, regardless of whether any fees have been paid previously in respect of those deposits.

(iv) Making a New Deposit

The depositor is required to complete model form BP/2 when making a new deposit and to supply copies of the relevant documents required by Rule 6.2. The receipt and viability statement for a new deposit are issued on mandatory “international forms” BP/5 and BP/9, respectively.

2. Furnishing of Samples

(a) Requests for Samples

The KCTC advises third parties of the correct procedures to follow in order to make a valid request. In the case of requests requiring proof of entitlement, the KCTC will provide requesting parties with copies of model request form BP/12 and/or request forms used by individual industrial property offices (where it has been supplied with such forms).

The KCTC furnishes samples on the basis that it is the responsibility of the requesting party to ensure that he complies with any relevant health and safety requirements. When responding to requests from overseas, the KCTC assumes that the requesting party has met the import requirements of his own country.

All samples of microorganisms furnished by the KCTC are from batches of its own preparations of the microorganisms.

(b) Notification of the Depositor

Depositors are notified on model form BP/14 when samples of their microorganisms have been furnished to third parties.

(c) Cataloguing of Budapest Treaty Deposits

The KCTC does not list Budapest Treaty deposits in its published catalog.

3. Schedule of Fees

	Won
(a) <u>Storage</u>	
– original deposit	600,000
– new deposit	50,000
(b) <u>Issuance of viability statement</u>	
– if the depositor requiring a viability statement has also requested a viability test	20,000
– in other cases	10,000
(c) <u>Furnishing of samples</u>	50,000
(d) <u>Issuance of an attestation under Rule 8.2</u>	10,000
(e) <u>Communication of information under Rule 7.6</u>	10,000

4. Guidance for Depositors

The KCTC does not at present produce specific written notes for the guidance of prospective depositors, but is always ready to give advice by telephone or letter.

LV – LATVIA

MICROBIAL STRAIN COLLECTION OF LATVIA (MSCL)

University of Latvia, Faculty of Biology
blvd. Kronvalda 4
RIGA LV-1586
Latvia

Telephone : 00371-7322914
Fax : 00371-7325657
E-mail : indrikis @ laima. acad. latnet. lv

(See *Industrial Property and Copyright*, 1997, p. 190)

1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

Bacteria (including actinomycetes), microscopic fungi (including yeasts) and plasmids in a host that can be preserved without significant changes to their properties by freeze-drying or during storage on slant agar slope.

(b) Technical Requirements and Procedures

(i) Form and Quantity

Cultures submitted to MSCL for deposit must be in the form of agar stabs (slants) or lyophilized. The minimum number of replicates that must be provided by the depositor is five stabs (slants) or 25 lyophilized ampoules.

(ii) Time Required for Viability Testing

The average time required for testing the viability of various microorganisms accepted by MSCL is 7 days, but in some cases viability testing may take 20 days.

(iii) Depositor Checks and Renewal of Stocks

The MSCL prepares its own batches by subculturing material originally supplied by the depositor. New batches are prepared for renewal of diminishing stocks. MSCL routinely asks the depositor to check the authenticity of the preparations made by the MSCL at the time of deposit from material supplied by the depositor. The MSCL routinely checks newly received deposits for contamination and, if they are found contaminated, returns them to the depositor. The MSCL stores original material supplied by the depositor.

(c) Administrative Requirements and Procedures

(i) General

Language. The official language of the MSCL is Latvian. Communications are accepted in English, German and Russian.

Contract. The MSCL does not enter into any written contract with the depositor defining the liabilities of either party but, by signing the MSCL deposit forms, the depositor surrenders any right to withdraw his deposit during the required storage period and accepts that the microorganisms will be distributed according to the relevant patent requirements.

Import and/or Quarantine Regulations. The kinds of microorganisms accepted for deposit by the MSCL are not subject to import or quarantine regulations. The MSCL does not advise the depositor of the procedures he must follow to obtain an import permit.

(ii) Making the Original Deposit

Requirements to be Met by the Depositor. Depositors are required to complete form MSCL-BP/1 (the equivalent of model form BP/1) which is the accession form used for Budapest Treaty deposits. They must complete the equivalent of model form BP/2 when making a new deposit and the equivalent of model form BP/7 when communicating a later designation or amendment of a scientific description and/or taxonomic designation.

Official Notifications to the Depositor. Except the mandatory “international forms,” official notifications are not issued on standard forms.

Unofficial Notifications to the Depositor. If requested, the MSCL will telephone or telefax the date of deposit and the accession number before the official receipt is issued, but only after a positive viability test has been obtained. The MSCL will similarly communicate the results of the viability test before the viability statement is issued.

Supply of Information to a Patent Agent. The MSCL does not routinely ask the depositor for the name and address of his patent agent. However, if requested, the MSCL will send copies of the receipt and viability statement to both the depositor and his patent agent.

(iii) Converting a Previous Deposit

Deposits made outside the provisions of the Budapest Treaty may be converted by the original depositor to deposits under the Budapest Treaty only if they were originally made for patent purposes. The administrative requirements for conversion are similar to those to be met in respect of an original deposit made under the Treaty.

All conversions are subject to the storage fee normally levied for Budapest Treaty deposits.

(iv) Making a New Deposit

The depositor is required to complete the equivalent of model form BP/2 when making a new deposit, and to supply copies of the relevant documents required by Rule 6.2. The receipt and viability statement for a new deposit are issued on mandatory “international forms” BP/5 and BP/9.

2. Furnishing of Samples

(a) Requests for Samples

The MSCL advises third parties of the correct procedures to follow in order to make a valid request. In the case of requests requiring proof of entitlement, the MSCL will provide requesting parties with copies of model request form BP/12 and/or request forms used by individual industrial property offices (where it has been supplied with such forms). All samples furnished by the MSCL are from batches of its own preparations.

(b) Notification of Depositor

Depositors are notified on model form BP/14 when samples of their microorganism have been furnished to third parties.

(c) Cataloguing of Budapest Treaty Deposits

The MSCL does not list Budapest Treaty deposits in its published catalog.

3. Schedule of Fees

	Latvian Lats (Ls)
(a) <u>Storage</u>	300
(b) <u>Issuance of viability statement</u>	30
(c) <u>Furnishing of samples</u>	30 (plus cost of transport)

4. Guidance for Depositors

At present the MSCL does not have specific written notes for the guidance of depositors, but is always ready to offer advice by telephone, telefax or e-mail.

NL – NETHERLANDS

CENTRAALBUREAU VOOR SCHIMMELCULTURES (CBS)

Oosterstraat 1
Postbus 273
NL-3740 AG BAARN
Netherlands

Telephone: (3135) 54 81211
Telefax: (3135) 54 16142
Internet home page: <http://www.cbs.knaw.nl>

(See *Industrial Property*, 1981, pp. 219 and 221; 1984, p. 148; 1985, p. 235; 1991, p. 423; *Intellectual Property Laws and Treaties*, 2000, p. 4.)

1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

Fungi; yeasts; bacteria; plasmids in pure form or in a host of the kinds accepted by CBS and phages that can be maintained with routine laboratory techniques without significant modification during appropriate storage at low temperature, in liquid nitrogen or during storage in the lyophilized state. Strains requiring special cultural conditions can be accepted under special conditions and are subject to additional fees (on request).

The following bacteria of pathogenic group I (PG I: World Health Organization (WHO) definition: low individual and community risk) are accepted only when they can be maintained by Rijks Instituut voor Volksgezondheid en Milieuhygiëne (RIVM), Centraal Diergeneeskundig Instituut (CDI) or the Royal Institute for Tropical Research:

– Bordetella (all species), Brucella (all species), Erysipelothrix (all species), Leptospira (all species), Listeria (all species), Mycobacterium paratuberculosis, Pasteurella (all species), Treponema (all species).

The following bacteria of pathogenic group II (PG II WHO definition: severe individual and limited community risk) are accepted only when they can be maintained by RIVM or CDI:

– Bartonella (all species), Francisella (all species), Mycobacterium bovis, Mycobacterium tuberculosis, Pseudomonas mallei, Pseudomonas pseudomallei.

The following bacteria are not accepted:

– Bacillus anthracis and Yersinia pestis.

In cases of cultures considered to be of special hazard, the CBS should be contacted before sending them.

(b) Technical Requirements and Procedures

(i) Form and Quantity

The CBS prefers to receive microorganisms submitted for deposit as lyophilized preparations. Where it is undesirable or impossible to supply lyophilized preparations, active cultures growing in or on a suitable nutrient medium are acceptable. The minimum number of replicates that must be supplied by the depositor when making his deposit is as follows:

fungi	12 lyophilized cultures; or 2 agar cultures;
yeasts	12 lyophilized plus 1 agar culture; or 2 agar cultures;
bacteria	12 lyophilized plus 1 agar culture; or 3 agar cultures;
plasmids (in hosts)	12 lyophilized plus 1 agar culture; or 3 agar cultures;
plasmids (purified DNA)	minimum quantity of 50 g;
phages	10 ml with a titre of at least 10 ⁹ pfu/ml.

In cases where the depositor is unable to supply lyophilized preparations, the CBS prepares lyophilized cultures at the time of deposit from the material supplied by the depositor at a fee of Hfl 175 for 12 vials. The preparation of a phage lysate with a sufficiently high titre can be done at a fee of Hfl 1,000. The depositor is required to check the authenticity of a sample of the batches prepared by the CBS, and to inform the CBS of the result. Plasmid stocks are not prepared by the CBS.

(ii) Time Required for Viability Testing

The average length of time required for testing viability of the various kinds of microorganisms accepted by the CBS is given below, but depositors should realize that occasionally viability testing may take longer. This is especially likely if unusual antibiotics or other additives are necessary in the medium.

fungi, bacteria, plasmids in hosts or purified DNA, ¹ phages	2 weeks
yeasts	1 week

¹ A "viability test" for plasmids consists of transforming a suitable host with the plasmid. If the host is transformed, the "viability test" is regarded as positive.

(iii) Depositor Checks and Renewal of Stocks

The CBS routinely asks the depositor to check the authenticity of the deposited preparations after transfers. New batches of cultures are prepared whenever it is necessary to renew diminishing stocks.

Whichever method is used for preparing batches of samples for distribution, the CBS always keeps a portion of the original material supplied by the depositor.

(c) Administrative Requirements and Procedures

(i) General

Language. The official language of the CBS is English. Communications are also accepted in Dutch, German and French. The preferred language for correspondence is English.

Contract. The CBS does not enter into any written contract with the depositor defining the liabilities of either party but, by signing the CBS deposit forms, the depositor surrenders any right to withdraw his deposit during the required storage period and accepts that the microorganism will be distributed according to the relevant patent requirements.

Import and/or Quarantine Regulations. Certain microorganisms are subject to import and/or quarantine regulations. The CBS will advise depositors about these and will make the necessary arrangements for transportation and, if necessary, licenses (fees on request). The CBS should be contacted for precise instructions in this regard, and, in cases of plant pathogens, further information may be obtained from: Plantenziektenkundige Dienst (PD), Geertjesweg 15, Postbus 9102, 6700 NC Wageningen, Netherlands.

The CBS should be contacted in advance if deposit of any of the following plant pathogenic bacteria is intended:

Agrobacterium rhizogenes, *Corynebacterium flaccumfaciens*, *C. insidiosum*, *C. michiganense*, *C. sepedonicum*, *Erwinia amylovora*, *E. stewartii*, *E. tracheiphila*, *Pseudomonas caryophylli*, *P. solanacearum*, *P. syringae*, pv *glycinae*, pv *persicae*, pv *pisi*, *P. woodsii*, *Xanthomonas ampelina*, *X. campestris*, pv *citri*, pv *corylina*, pv *oryzae*, pv *oryzicola*, pv *phaseoli*, pv *pruni*, pv *vesicatoria*, *X. fragariae*, *X. populi*.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. The depositor is required to complete the CBS accession form for patent deposits and model form BP/1. In the event of a later indication or amendment of the scientific description and/or proposed taxonomic designation, the depositor must complete model form BP/7.

Official Notifications to the Depositor. The receipt and viability statement are issued on mandatory “international forms” BP/4 and BP/9, respectively. Attestation of receipt of a later indication or amendment of the scientific description and/or proposed taxonomic designation is issued on form BP/8. Standard forms are not used for other official notifications.

Unofficial Notifications to the Depositor. If requested, the CBS will telephone or telex the date of deposit and accession number after the microorganism has been received, but before the official receipt is issued. The CBS similarly will telephone or telex the result of the viability test before the official viability statement is issued.

Supply of Information to a Patent Agent. The CBS does not ask the depositor to give the name and address of his patent agent. Depending on the wishes of the depositor, the CBS will supply copies of the receipt and viability statement either to the depositor or to his patent agent, but not to both.

(iii) Converting a Previous Deposit

Deposits made outside the provisions of the Budapest Treaty may be converted by the original depositor to Budapest Treaty deposits, whether or not they were originally deposited for patent purposes. All converted deposits are subject to the storage fee normally levied for Budapest Treaty deposits, with the exception of deposits previously made under the European Patent Convention. The administrative requirements for conversion are the same as those to be met in respect of an original deposit made under the Treaty, except that requirements relating to import and/or quarantine procedures do not apply.

(iv) Making a New Deposit

When making a new deposit, the depositor is required to complete model form BP/2 and to send copies of the relevant documents (Rule 6.2); otherwise the procedure is similar to that when making an original deposit.

2. Furnishing of Samples

(a) Requests for Samples

The CBS advises third parties of the correct procedures to follow in order to make a valid request. In the case of requests requiring proof of entitlement, the CBS will provide requesting parties with copies of model request form BP/12 and/or request forms used by individual industrial property offices (where it has been supplied with such forms).

Notwithstanding any entitlement of third parties to receive samples under patent regulations, in the case of potentially hazardous microorganisms, the CBS will first confirm that the requesting party is competent to handle them. Samples are not released to private persons not engaged in a relevant profession. When responding to requests from overseas, the CBS assumes that the requesting party has met the import requirements of his own country.

Samples of yeasts and of bacteria furnished by the CBS are usually from batches of its own preparations, but samples of other microorganisms are usually from preparations supplied by the depositor.

(b) Notification of the Depositor

Unless he has waived his right to be so notified, the CBS notifies the depositor by letter when samples of his microorganisms have been furnished to third parties. The CBS offers a reduced fee for storage to depositors who waive their right to be notified of the release of samples (see below).

(c) Cataloguing of Budapest Treaty Deposits

The CBS does not list Budapest Treaty deposits in its published catalog.

3. Schedule of Fees

	NL Guilder
(a) <u>Deposition for 30 years, in conformity with Rule 11.4(g)</u>	1,250
(b) <u>Conversion of a deposit made outside the Budapest Treaty into a deposit according to the Budapest Treaty</u>	1,250
(c) <u>Preservation of stockmaterial for the deposition of 30 years</u>	
– set of 10 ampoules freeze-dried material	250
– set of 10 frozen straws	300
(d) <u>Issuance of viability statement, except where Rule 10.2(e)</u>	
– if the viability test is to be carried out	160
– based on the last viability test	50
(e) <u>Communication of information under Rule 7.6</u>	50
(f) <u>Attestation of receipt in conformity with Rule 8.2</u>	50

NL Guilder

(g)	<u>Furnishing samples</u>	
–	in accordance with Rule 11.2(ii), 11.3(a) and 11.3(b)	200
–	in accordance with Rule 11.2(i)	
–	agar slant	75
–	freeze-dried ampoule	25
(h)	<u>Surcharge to cover bank and administrative costs</u>	20

4. Guidance for Depositors

The CBS does not produce a standard letter or guidance notes for prospective depositors, but from time to time guidance is provided in the CBS Newsletter.

RU – RUSSIAN FEDERATION

NATIONAL RESEARCH CENTER OF ANTIBIOTICS (NRCA)

Nagatinskaya Street 3-a
MOSCOW 113105
Russian Federation

Tel./Fax: (7-095) 111 42 38

(See *Industrial Property*, 1987, p. 250; 1992, p. 276; *Industrial Property and Copyright*, 1997, p.334; *Intellectual Property Laws and Treaties*, 2000, p. 42.)

1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

Bacteria (including actinomycetes) and microscopic fungi (including yeasts) for essentially medical purposes are accepted for deposit, to the exclusion of microorganisms that cause disease in man and animals and microorganisms that are toxicogenic for plants or require them to be quarantined.

(b) Technical Requirements and Procedures

(i) Form and Quantity

Cultures submitted to NRCA for deposit must be in the form of agar stabs or lyophilized. The minimum number of replicates that must be provided by the depositor is five stabs or 50 ampoules.

(ii) Time Required for Viability Testing

The average length of time required for testing the viability of the different kinds of microorganisms accepted for deposit by NRCA is given below; however, depositors should realize that in some cases viability testing may take longer, as indicated by the figures in brackets:

bacteria	15 days (or up to 30 days)
fungi	10 days (or up to 30 days)
yeasts	5 days (or up to 30 days)

(iii) Depositor Checks and Renewal of Stocks

NRCA prepares its own batches by subculturing material originally supplied by the depositor. As a rule, new batches are prepared from these and by subculturing NRCA's own preparations as necessary thereafter for the renewal of diminishing stocks. NRCA routinely

asks the depositor to check the authenticity of the preparations made by NRCA at the time of deposit from material supplied by the depositor. NRCA routinely checks newly received deposits for contamination and, if they are found contaminated, it returns them to the depositor.

NRCA stores original material supplied by the depositor.

(c) Administrative Requirements and Procedures

(i) General

Language. The official language of NRCA is Russian. Communications may also be exchanged in English.

Contract. NRCA does not enter into a contract with the depositor.

Import and/or Quarantine Regulations. The kinds of microorganisms accepted for deposit by NRCA are not subject to import or quarantine regulations.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. The depositor must complete form BP/1 when making the original deposit and when converting a deposit made outside the Budapest Treaty. He must complete form BP/2 when making a new deposit and form BP/7 when communicating a later designation or amendment of a scientific description and/or taxonomic designation.

Official Notifications to the Depositor. Official notifications are not issued on standard forms other than the mandatory “international forms” used for the receipt and viability statement.

Unofficial Notifications to the Depositor. NRCA does not notify unofficially to the depositor the date of deposit and the accession number nor the result of the viability test before the relevant receipt and viability statement are issued.

Supply of Information to a Patent Agent. NRCA does not ask the depositor to supply the name and address of his patent attorney. However, if requested, it will supply copies of the official receipt and viability statement to both the depositor and his attorney.

(iii) Converting a Previous Deposit

Deposits made outside the provisions of the Budapest Treaty may be converted by the original depositor to deposits under the Budapest Treaty when they were originally deposited for patent purposes. The administrative requirements for conversion are the same as those to be met in respect of an original deposit made under the Treaty.

(iv) Making a New Deposit

When making a new deposit, the depositor is not required to meet any requirement additional to those provided for in connection with the original deposit.

2. Furnishing of Samples

(a) Requests for Samples

NRCA advises third parties of the correct procedure to follow in order to make a valid request.

When responding to requests for samples from overseas, NRCA assumes that the requesting party has met the import requirements of his own country.

(b) Notification of the Depositor

Depositors are notified on model form BP/14 when samples of their microorganisms have been furnished to third parties.

(c) Cataloguing of Budapest Treaty Deposits

NRCA does not list deposits made under the Budapest Treaty in its published catalog.

3. Schedule of Fees

	US\$
(a) <u>Storage</u>	
– for the deposit of a microorganism and its storage for 30 years	500
(b) <u>Issuance of viability statement</u>	100
(c) <u>Furnishing of samples</u>	100
(d) <u>Communication of information under rule 7.6 or issuance of attestation under Rule 8.2</u>	25
(e) <u>Others fees (communication, carriage)</u>	According to effective cost

The above amounts do not include the mailing charges, which are invoiced separately at cost.

4. Guidance for Depositors

NRCA does not at present produce a standard letter or guidance notes for prospective depositors.

RU – RUSSIAN FEDERATION

RUSSIAN COLLECTION OF MICROORGANISMS (VKM)

Prospekt Naouki No. 5
PUSHCHINO 142292 (MOSCOW Region)
Russian Federation

Tel.: (7095) 9257 448
Fax: (7095) 9233 602
Internet home page: <http://www.vkm.ru/>

(See *Industrial Property*, 1987, p. 249; 1992, p. 276; 1994, p. 317.)

1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

Bacteria (including actinomycetes) and microscopic fungi (including yeasts), also if they are carriers of recombinant DNA, are accepted for deposit, to the exclusion of microorganisms that cause disease in man and animals and microorganisms that have a toxicogenic effect on plants or require them to be quarantined.

VKM does not accept for deposit:

- microorganisms whose manipulation needs physical containment levels P2, P3 or P4, as described in “Laboratory Safety Monographs”;
- microorganisms liable to require viability testing that VKM is technically not able to carry out and mixtures of undefined and/or unidentifiable microorganisms.

(b) Technical Requirements and Procedures

(i) Form and Quantity

Cultures submitted to VKM for deposit must be in the form of agar stabs or lyophilized. The minimum number of replicates that must be provided by the depositor is five stabs or 50 ampoules.

(ii) Time Required for Viability Testing

The average length of time required for testing the viability of the different kinds of microorganisms accepted for deposit by VKM is given below; however, depositors should realize that in some cases viability testing may take longer, as indicated by the figures in brackets:

bacteria	7 days (or up to 30 days)
fungi	7 days (or up to 25 days)
yeasts	7 days (or up to 14 days)

(iii) Depositor Checks and Renewal of Stocks

VKM prepares its own batches by subculturing material originally supplied by the depositor. As a rule, new batches are prepared from these and by subculturing VKM's own preparations as necessary thereafter for the renewal of diminishing stocks. VKM routinely asks the depositor to check the authenticity of the preparations made by VKM at the time of deposit from material supplied by the depositor. VKM routinely checks newly received deposits for contamination and, if they are found contaminated, it returns them to the depositor.

VKM stores original material supplied by the depositor.

(c) Administrative Requirements and Procedures

(i) General

Language. The official language of VKM is Russian. Communications may also be exchanged in English.

Contract. VKM does not enter into a contract with the depositor. Completion by the depositor of form BP/1 is considered sufficient.

Import and/or Quarantine Regulations. The kinds of microorganisms accepted for deposit by VKM are not subject to import or quarantine regulations. VKM does not advise the depositor on the procedures he must follow to obtain an import permit. To this effect, the depositor must check the applicable national regulations.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. The depositor must complete form BP/1 when making the original deposit and when converting a deposit made outside the Budapest Treaty. He must complete form BP/2 when making a new deposit and form BP/7 when communicating a later designation or amendment of a scientific description and/or taxonomic designation.

Official Notifications to the Depositor. Other than the mandatory "international forms", official notifications are not issued on standard forms.

Unofficial Notifications to the Depositor. VKM does not notify unofficially to the depositor the date of deposit and the accession number nor the result of the viability test before the relevant receipt and viability statement are issued.

Supply of Information to a Patent Agent. VKM does not ask the depositor to supply the name and address of his patent attorney. However, if requested, it will supply copies of the official receipt and viability statement to both the depositor or his attorney.

(iii) Converting a Previous Deposit

Deposits made outside the provisions of the Budapest Treaty may be converted by the original depositor to deposits under the Budapest Treaty, whether or not they were originally deposited for patent purposes. However, any deposits previously made free of charge are subject on conversion to the storage fee normally levied for Budapest Treaty deposits. The administrative requirements for conversion of a deposit not previously made for patent purposes are the same as those to be met in respect of an original deposit made under the Treaty.

(iv) Making a New Deposit

When making a new deposit, the depositor is not required to meet any requirement additional to those provided for in connection with the original deposit.

2. Furnishing of Samples

(a) Requests for Samples

VKM advises third parties of the correct procedure to follow in order to make a valid request and will supply such parties with copies of model request form BP/12 or request forms used by individual industrial property offices.

When responding to requests for samples from overseas, VKM assumes that the requesting party has met the import requirements of his own country.

(b) Notification of the Depositor

VKM does not notify depositors when samples of their microorganism have been furnished to third parties.

(c) Cataloguing of Budapest Treaty Deposits

VKM does not list deposits made under the Budapest Treaty in its published catalog.

3. Schedule of Fees

	US dollars
(a) <u>Storage</u>	300
(b) <u>Issuance of viability statements</u>	50
(c) <u>Furnishing of samples</u>	50

4. Guidance for Depositors

VKM does not at present produce a standard letter or guidance notes for prospective depositors.

RU – RUSSIAN FEDERATION

RUSSIAN NATIONAL COLLECTION OF INDUSTRIAL MICROORGANISMS (VKPM) GNII Genetika

Dorozhny proezd, 1
MOSCOW 113545
Russian Federation

Telephone: (7-095) 315 12 10
Telefax: (7-095) 315 05 01
E-mail: vkpm@vnigen.mks.su

(See *Industrial Property*, 1987, p. 248; 1992, p. 276; 1994, p. 276; *Intellectual Property Laws and Treaties*, 1998 p. 46.)

1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

Bacteria (including actinomycetes) and microscopic fungi (including yeasts) bacteriophages, plasmids (in host or as an isolated DNA), plant cell cultures, animal and human cell cultures (including hybridoma lines), except:

- microorganisms having properties which are or may be dangerous to health or the environment;
- microorganisms which need the special containment required for experiments.

Deposits containing recombinant DNA molecules do not require a physical containment level higher than level P2 as described in the National Institutes of Health “Guidelines for Research Involving Recombinant DNA Molecules” (USA).

(b) Technical Requirements and Procedures

(i) Form and Quantity

VKPM prefers to receive microorganisms submitted for deposit as lyophilized preparations. Where it is undesirable or impossible to supply lyophilized preparations, active cultures growing in or on a suitable nutrient medium are acceptable. The minimum number of replicates that must be supplied by the depositor is as follows:

fungi, yeasts, bacteria, plasmids (in host)	20 lyophilized cultures plus 1 agar culture, or 2 agar cultures
plasmids (purified DNA)	25 vials (100 ng each)
cell lines and hybridomas	25 frozen samples

bacteriophages	5x0.5ml (free cell lysate) (at least 10^8 pfu/ml)
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Bacteriophages and plasmids are required to be sent with a suitable host, if such a host is not available in the public collection of VKPM.

(ii) Time Required for Viability Testing

The average length of time requested for testing the viability of the various kinds of microorganisms accepted by VKPM is given below:

bacteria, plasmids in hosts	7 days
fungi, yeasts, plasmids as DNA, bacteriophages, cell lines, hybridomas	14 days

(iii) Depositor Checks and Renewal of Stocks

VKPM prepares its own lyophilized and/or frozen batches of bacteria and fungi at the time of deposit by subculturing material supplied by the depositor (but not from plasmids, bacteriophages, plant, animal and human cell cultures). New batches are prepared from these as necessary thereafter for the renewal of diminishing stocks. The depositor is required to test for authenticity samples from all batches prepared by VKPM.

Whatever the method used for preparing batches of samples for distribution, VKPM nevertheless stores a portion of the original material supplied by the depositor, if the culture supplied allows this.

(c) Administrative Requirements and Procedures

(i) General

Language. The official language of VKPM is Russian. Communications may also be exchanged in English.

Contract. VKPM does not enter into any written contract with the depositor defining the liabilities of either party, except the VKPM-BP/1 application form, which the depositor is required to complete.

Import and/or Quarantine Regulations. Certain microorganisms accepted for deposit by VKPM are subject to import regulations. VKPM may obtain on behalf of the depositor the necessary import permits; however, the depositor must supply information on the non-pathogenicity of the microorganisms.

Microorganisms accepted for deposit by VKPM must not be subject to quarantine regulations.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. The depositor is required to complete the VKPM-BP/1 accession form for patent deposits (the equivalent of model form BP/1). In the event of a later indication or amendment of the scientific description and/or proposed taxonomic designation, the depositor must complete model form BP/7.

Official Notifications to the Depositor. The receipt and the viability statement are issued on mandatory “international forms” BP/4 and BP/9, respectively. Notification of the furnishing of samples to third parties is issued on model form BP/14. VKPM uses the standard form in preference for the other official notifications.

Unofficial Notifications to the Depositor. If requested, VKPM will telephone or telefax the date of deposit and accession number before the official receipt is issued, but only after the viability test has been carried out and has given a positive result. VKPM will similarly communicate the results of the viability test before the viability statement is issued.

Supply of Information to a Patent Agent. If requested, VKPM supplies copies of the receipt and viability statement to the depositor’s patent agent.

(iii) Converting a Previous Deposit

Deposits made outside the provisions of the Budapest Treaty may be converted to Budapest Treaty deposits, provided that they were originally made for patent purposes, or they were confidential for safe-keeping. All converted deposits are subject to the payment of the storage fee normally levied for Budapest Treaty deposits. The administrative requirements for conversion of a deposit are the same as those to be met by an original deposit made under the Treaty.

(iv) Making a New Deposit

When making a new deposit, the depositor is required to complete model form BP/2 and to send copies of the relevant documents specified in Rule 6.2; otherwise the procedure is similar to that when making an original deposit.

2. Furnishing of Samples

(a) Requests for Samples

VKPM advises third parties of the correct procedure to follow in order to make a valid request and will supply such parties with copies of model request form BP/12.

(b) Notification of the Depositor

VKPM notifies the depositor on form BP/14 each time a sample of his deposit is furnished to a third party.

(c) Cataloguing of Budapest Treaty Deposits

At the request of the depositor, VKPM lists Budapest Treaty deposits in its published catalog. All microorganisms that are the subject of granted and published patents of the Russian Federation are listed in the catalog.

3. Schedule of Fees

	US dollars
(a) <u>Storage</u> (30 years)	300
(b) <u>Issuance of viability statement</u>	100
– bacteria, fungi, bacteriophages, plasmids	100
– plasmid DNA	150
– cell lines, hybridomas	150
(c) <u>Furnishing of samples</u>	
– bacteria, fungi, bacteriophages, plasmids	100
– cell lines, hybridomas	150
(d) <u>Communication of information under Rule 7.6 or issuance of an attestation under Rule 8.2</u>	25
(e) <u>Other fees (communication, carriage)</u>	according to effective cost

4. Guidance for Depositors

VKPM produces notes for the guidance of potential depositors.

SK – SLOVAKIA

CULTURE COLLECTION OF YEASTS (CCY)

Institute of Chemistry
Slovak Academy of Sciences
Dúbravská cesta 9
842 38 BRATISLAVA
Slovakia

Telephone: (42-7) 378 26 25

Telefax: (42-7) 37 38 11

Internet home page: <http://nic.savba.sk/sav/inst/chem/intro/html>

(See *Industrial Property*, 1992, p. 211.)

1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

- Yeasts that can be preserved without significant change to their properties by liquid nitrogen freezing or in active culture.
- Yeasts that can be maintained with normal laboratory techniques without significant modification during storage in liquid nitrogen or during storage on slant agar slope.

(b) Technical Requirements and Procedures

(i) Form and Quantity

The CCY accepts microorganisms for deposit as either lyophilized preparations or active cultures. The minimum number of replicates that must be provided by the depositor when making his deposit is four for lyophilized preparations and two for agar slope cultures.

(ii) Time Required for Viability Testing

The average length of time required for testing the viability of yeasts cultures by the CCY is six days, but in some cases viability testing may take as long as 14 days.

(iii) Depositor Checks and Renewal of Stocks

The CCY prepares its own batches of yeasts by subculturing the material supplied by the depositor. New batches are prepared from the depositor's original material for the renewal of stocks. The CCY routinely asks the depositor to check the authenticity of the preparations made by the CCY at the time of deposit from material supplied by the depositor.

The CCY stores original material supplied by the depositor.

(c) Administrative Requirements and Procedures

(i) General

Language. The official language of the CCY is Slovak. Communications are also accepted in English.

Contract. The CCY does not enter into a written contract with the depositor defining the liabilities of either party. However, by signing the CCY deposit form, the depositor surrenders any right to withdraw his microorganisms during the required storage period.

Import and/or Quarantine Regulations. Import and/or quarantine regulations do not apply to the kinds of microorganisms accepted by the CCY for deposit.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. The depositor is required to complete the equivalent of model form BP/1, which is used by the CCY as its accession form for Budapest Treaty deposits. In the event of a later indication or amendment of the scientific description and/or proposed taxonomic designation, and a request for attestation that the CCY has received such information, the depositor must complete the equivalent of model form BP/7.

Official Notifications to the Depositor. The receipt and viability statement are issued on mandatory “international forms” BP/4 and BP/9, respectively. Attestation of receipt of a later indication or amendment of the scientific description and/or proposed taxonomic designation is issued on the equivalent of model form BP/8. Notification of the furnishing of samples to third parties is issued on model form BP/14. Standard forms are not used for other official notifications.

Unofficial Notifications to the Depositor. The CCY does not telephone or telex the date of deposit, accession number or results of the viability test in advance of the relevant official notifications.

Supply of Information to a Patent Agent. The CCY does not routinely ask the depositor for the name and address of his patent agent. However, if requested, the CCY will send copies of the receipt and viability statement to both the depositor and his patent agent.

(iii) Converting a Previous Deposit

Deposits made outside the provisions of the Budapest Treaty may be converted by the original depositor to Budapest Treaty deposits, whether or not they were originally deposited for patent purposes. All conversions are subject to the storage fee normally levied for Budapest Treaty deposits, regardless of whether any fee had previously been paid in respect of those deposits.

The administrative requirements for conversion are the same as those to be met in respect of an original deposit made under the Treaty.

(iv) Making a New Deposit

The depositor is required to complete model form BP/2 when making a new deposit and to supply copies of the relevant documents required by Rule 6.2. The receipt and viability statement are issued on mandatory “international forms” BP/5 and BP/9, respectively.

2. Furnishing of Samples

(a) Requests for Samples

The CCY advises third parties of the correct procedures to follow in order to make a valid request. In the case of requests requiring proof of entitlement, the CCY will provide requesting parties with copies of model request form BP/12 and/or request forms used by individual industrial property offices (where it has been supplied with such forms).

When responding to requests from overseas, the CCY assumes that the requesting party has met the import requirements of his own country.

All samples furnished by the CCY are from batches of its own preparations.

(b) Notification of the Depositor

Depositors are notified on model form BP/14 when samples of their microorganisms have been furnished to third parties.

(c) Cataloguing of Budapest Treaty Deposits

The CCY does not list Budapest Treaty deposits in its published catalog.

3. Schedule of Fees

	Slovak crowns
(a) <u>Storage</u>	20,000
(b) <u>Issuance of viability statements</u>	1,000
(c) <u>Furnishing of samples</u>	1,200

4. Guidance for Depositors

The CCY does not produce a standard letter or guidance notes for prospective depositors.

US – UNITED STATES OF AMERICA

AGRICULTURAL RESEARCH SERVICE CULTURE COLLECTION (NRRL)

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United States of America

Telephone: (309) 685 4011
Internet home page: <http://nrml.ncaur.usda.gov>

(See *Industrial Property*, 1981, pp. 22, 23 and 121; 1983, p. 248; 1987, p. 247.)

1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

Progeny of strains of agriculturally and industrially important bacteria, yeasts, moulds, Actinomycetales, and plasmids when they are inserted into microorganisms, except:

- Actinobacillus (all species), Actinomyces (anaerobic/ microaerophilic--all species), Arizona (all species), Bacillus anthracis, Bartonella (all species), Bordetella (all species), Borrelia (all species), Brucella (all species), Clostridium botulinum, C.chauvoei, C.haemolyticum, C.histolyticum, C.novyi, C.septicum, C.tetani, Corynebacterium diphtheriae, Cor. equi, Cor. haemolyticum, Cor. pseudotuberculosis, Cor. pyogenes, Cor. renale, Diplococcus (all species), Erysipelothrix (all species), Escherichia coli (all enteropathogenic types), Francisella (all species), Haemophilus (all species), Herellea (all species), Klebsiella (all species), Leptospira (all species), Listeria (all species), Mima (all species), Moraxella (all species), Mycobacterium avium, M.bovis, M.tuberculosis, Mycoplasma (all species), Neisseria (all species), Pasteurella (all species), Pseudomonas pseudomallei, Salmonella (all species), Shigella (all species), Sphaerophorus (all species), Streptobacillus (all species), Streptococcus (all pathogenic species), Treponema (all species), Vibrio (all species), Yersinia (all species);
- Blastomyces (all species), Coccidioides (all species), Cryptococcus neoformans, C. uniguttulatus, Histoplasma (all species), Paracoccidioides (all species);
- all viral, Rickettsial and Chlamydial agents;
- agents which may introduce or disseminate any contagious or infectious disease of animals, humans or poultry and which would require a permit for entry and/or distribution within the United States of America;
- agents which are classified as plant pests and which would require a permit for entry and/or distribution within the United States of America;
- mixtures of microorganisms;

- fastidious microorganisms which would require (in the view of the Curator) more than reasonable attention in handling and preparation of lyophilized material;
- phages not inserted in microorganisms;
- monoclonal antibodies;
- all cell lines;
- plasmids not inserted in microorganisms.

The Collection will accept recombinant strains of microorganisms, strains containing recombinant DNA molecules, strains containing their own naturally occurring plasmid(s), strains containing inserted naturally occurring plasmids(s) from another host, strains containing inserted constructed plasmid(s), and strains containing viruses of any kind, excluding those already listed as nonacceptable, only if the deposit document accompanying the microbial preparation(s) includes a clear statement that progeny of the strain(s) can be processed at a Physical Containment Level of P1 or less and Biological Containment requirements meet all other criteria specified by the U.S. Department of Health and Human Services, National Institutes of Health; “Guidelines for Research Involving Recombinant DNA Molecules, December 1978” (Federal Register Vol. 43, No. 247-Friday, December 22, 1978) and any subsequent revisions.

(b) Technical Requirements and Procedures

(i) Form and Quantity

Bacteria, fungi and yeasts are accepted as slant, stab or broth cultures, or as lyophilized preparations. If the depositor wishes the NRRL to distribute his own lyophilized preparations, he must supply these preparations in tubes of overall dimensions no greater than 50mm in length and 6mm outside diameter. The minimum number of replicates that must be provided by the depositor when making his deposit is as follows:

for bacteria, fungi and yeasts, the NRRL requires the deposit of one or more preparations (slants, stabs, or lyophilized preparations) if the NRRL is to distribute its own preparations. If the NRRL is to distribute depositor’s preparations, 30 lyophilized preparations must be deposited.

(ii) Time Required for Viability Testing

The average length of time required for testing the viability of the various kinds of microorganisms accepted by the NRRL is given below, but depositors should realize that in some cases viability testing may take longer, as indicated by the figures in brackets:

bacteria	3 days (or up to 15 days)
fungi	10 days (or up to 15 days)
yeasts	10 days (or up to 20 days)

(iii) Depositor Checks and Renewal of Stocks

The NRRL stores and distributes lyophilized material supplied by the depositor, if this is his wish, or it makes its own lyophilized preparations by subculture of, or directly from, active material supplied by the depositor. New batches are prepared as necessary for the renewal of diminishing stocks. The NRRL requires the depositor to check the authenticity of its lyophilized preparations. The viability statement issued by the NRRL contains a section in which the depositor can record the result of this test. If the depositor does not inform the NRRL of the results of this test within three months, the NRRL assumes that its preparations are equivalent to the depositor's original deposit.

The NRRL does not accept plasmids, except when they are contained in a living host microorganism.

Whichever method is used for preparing batches of samples for distribution, the NRRL stores a portion of the original prepared and deposited material.

(c) Administrative Requirements and Procedures

(i) General

Language. The official language of the NRRL is English. Communications in any other language are not accepted.

Contract. The NRRL does not enter into any written contract with the depositor defining the liabilities of either party. However, by completing the NRRL deposition form, the depositor surrenders any right to withdraw his deposit during the required storage procedure, accepts NRRL policy on the handling and distribution of patent deposits, and accepts responsibility for the authenticity of NRRL preparations of his microorganism.

Import and/or Quarantine Regulations. Import and/or quarantine regulations do not apply to the kinds of microorganisms accepted by the NRRL for deposit.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. Depositors are required to complete the NRRL Budapest Treaty Deposition Form. The NRRL does not require a special form to be completed in the event of a later indication or amendment of the scientific description and/or proposed taxonomic designation, or for a request for attestation that the NRRL has received such information.

Official Notifications to the Depositor. The receipt and viability statement are issued on mandatory "international forms" BP/4 and BP/9, respectively. (NRRL has modified the latter to include a section in which the depositor can record the result of his authenticity check of NRRL preparations of his deposit--see (iv), below.) Notification of furnishing of a

sample to a third party is issued on form BP/14. Standard forms are not used for other official notifications.

Unofficial Notifications to the Depositor. If requested, the NRRL will telephone or telex the date of deposit and accession number after the microorganism has been received, but before the official receipt is issued. The result of the viability test is not so communicated.

Supply of Information to a Patent Agent. If requested, the NRRL will supply copies of the receipt and viability statement to the depositor's patent agent.

(iii) Converting a Previous Deposit

The NRRL does not permit the conversion of deposits not originally made for patent purposes to Budapest Treaty deposits. The administrative requirements for converting a deposit previously made for patent purposes are the same as those to be met with respect to an original deposit made under the Treaty, except that no fee is payable.

(iv) Making a New Deposit

The NRRL does not require the depositor to complete a standard form when making a new deposit, but he is asked to supply an acknowledgment that the new deposit is the same as the original deposit (Article 4), and to send copies of the relevant documents (Rule 6.2).

2. Furnishing of Samples

(a) Requests for Samples

The NRRL does not advise third parties of the correct procedures to follow in order to make a valid request for samples. In the case of requests requiring proof of entitlement, third parties requesting a sample under European Patent Office regulations are supplied with the relevant EPO form, but otherwise the NRRL does not supply copies of model request form BP/12 or request forms used by other individual industrial property offices; these must be obtained from the appropriate industrial property office.

Although the NRRL does not knowingly maintain hazardous microorganisms or those requiring a permit to be worked with in the United States of America, the requesting party must be "skilled in the art" (of microbiological practice) before any microorganisms are shipped. If a microorganism being requested is a known producer of a restricted substance, e.g., a hallucinogen, the requesting party must furnish his drug registration number before he can be supplied with a sample. When responding to requests from overseas, the NRRL assumes that the requesting party has met the import requirements of his own country.

Samples of bacteria, fungi and yeasts furnished by the NRRL may be from batches of its own lyophilized preparations or from lyophilized preparations supplied by the depositor, depending on the wishes expressed by the latter at the time of deposit (see 1(b), above).

(b) Notification of the Depositor

Unless he has waived his right to be so notified, the NRRL notifies the depositor on form BP/14 each time a sample of his deposit is furnished to a third party.

(c) Cataloguing of Budapest Treaty Deposits

The NRRL does not publish any catalog.

3. Schedule of Fees

	US dollars
(a) <u>Storage</u>	500
(b) <u>Furnishing of samples</u>	20

Agricultural Research Service (USDA) laboratories and ARS cooperators are exempt from payment of fees.

4. Guidance for Depositors

The NRRL makes available a detailed statement on policies and procedures and a standard letter of explanation.

US – UNITED STATES OF AMERICA

AMERICAN TYPE CULTURE COLLECTION (ATCC)

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(See *Industrial Property*, 1981, pp. 20 and 121; 1982, pp. 147 and 220; 1985, p. 163; 1986, pp. 295, 296 and 372; 1989, p. 119; 1991, p. 107; 1992, p. 54; *Industrial Property and Copyright*, 1995, p. 204; 1996, pp. 147 and 148; 1997, p.17; *Intellectual Property Law and Treaties*, 1998, p. 45; 1999, p. 61; May 2000.)

1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

Algae, embryos, animal viruses,¹ bacteria, fungi, human, animal and plant cell cultures, hybridomas, molds, oncogenes, phages, plant viruses, plasmids, protozoa, seeds, yeasts, eukaryotic DNA, murine embryos, mycoplasma, protozoa (pathogenic), and RNA.

For deposits consisting of or containing recombinant DNA molecules, the highest acceptable containment level is P3 as described in the 1980 National Institutes of Health “Guidelines for Research Involving Recombinant DNA Molecules” (US Department of Health and Human Services, Bethesda, Maryland, United States of America). The ATCC must be informed, in advance of accepting such deposits, of the containment level required.

(b) Technical Requirements and Procedures

(i) Form and Quantity

Cultures of microorganisms are accepted by the ATCC in any form. However, ATCC prefers frozen or freeze-dried material. The minimum number of replicates that must be provided by the depositor when making the deposit is as follows:

¹ Certain animal viruses may require viability testing in an animal host which the ATCC may be unable to provide. In such cases, the deposit cannot be accepted. Plant viruses which cannot be mechanically inoculated also cannot be accepted.

microorganisms (either containing a plasmid or not containing a plasmid), including bacteriophages, fungi, algae, yeast and protozoa	6 frozen or freeze-dried samples (0.5 ml each)
cell lines and hybridomas	25 frozen samples (2 –6 million cells each)
plasmids and vectors not in host (e.g., purified DNA, libraries associated rDNA material)	25 vials (100 ng each) and
animal and plant viruses	25 frozen or freeze-dried samples (1 ml each)
embryos	25 frozen samples(12 embryos constitute one sample)
plant tissue cultures	25 frozen samples
seeds	2500 seeds (100 labelled packets of 25 seeds each)

(ii) Time Required for Viability Testing

The average length of time required for testing the viability of the various kinds of microorganisms accepted by the ATCC is given below, but depositors should realize that in some cases viability testing may take longer, as indicated by the figures:

bacteria	3 - 7 days
fungi, molds, yeasts	5 - 7 days
algae	10 days
cell lines, hybridomas, oncogenes, bacteriophages	7 - 10 days
plasmids ² , phages and other rDNA	8 - 10 days
protozoa	10 or more days
animal and plant viruses	30 or more days
embryos	3 - 7 days

² For plasmids, “viability” testing consists of inserting the plasmid into a host. If the host is transformed, the “viability test” is regarded as positive.

plant tissue cultures, seeds

21 - 30 days

(iii) Depositor Checks and Renewal of Stocks

The ATCC prepares additional samples at the time of release of algae, bacteria, oncogenes, bacteriophages, yeasts, molds and, in rare cases, cell lines and hybridomas. Additional samples are prepared from the depositor's original material whenever necessary for the renewal of distribution stocks. The ATCC generally does not prepare its own batches of viruses, plasmids, seeds, plant tissue cultures, protozoa, cell lines and hybridomas. In such cases, the depositor is responsible for replenishing the stock to ensure that there is sufficient stock to make the deposit available to the general public for the required period of deposit.

The depositor is required to test for authenticity of samples of all batches of the microorganism prepared by the ATCC and to inform the ATCC of the result.

Whichever method is used for preparing batches of samples for distribution, the ATCC nevertheless stores a portion of the original material supplied by the depositor.

(c) Administrative Requirements and Procedures

(i) General

Language. The official language of the ATCC is English. Communications in any other language are not accepted.

Contract. The ATCC does not enter into any written contract with the depositor defining the liabilities of either party, except in the case of certain dangerous organisms, where the depositor must agree to accept and handle them at his own risk. Also, by completing the ATCC BP/1 deposit form, the depositor surrenders any right to withdraw his deposit during the required storage period and accepts that the microorganism will be distributed according to the relevant patent requirements.

Import and/or Quarantine Regulations. The ATCC must obtain an import permit from either or both the US Department of Agriculture and the US Public Health Service for the import of cell lines and viruses into the United States. Cell lines and viruses must be safety tested by the USDA for specific diseases. Material from Japan, Australia and the United Kingdom is tested in vitro, which takes about eight weeks and costs about \$500. Material from other countries must be tested in vivo, which takes about three months and costs about \$3,000.

As of May 1995, the US Department of Agriculture has determined that the following materials and products of animal origin from Canada, a country not restricted by the USDA for specified diseases, may enter the United States without a Veterinary Services import permit:

Research materials—(Examples: bacteria, viruses, cell lines, monoclonal and polyclonal antibodies, diagnostic test kits, and other kit components such as animal serum/blood).

These biologicals require a certificate on the depositor's letterhead stating that the material was manufactured in Canada and obtained from animals resident in Canada.

The ATCC requires the prospective depositor of a cell line or virus to complete a special form which asks for the information necessary to enable the ATCC to obtain an import permit. Obtaining such a permit usually takes four to six weeks. The ATCC will advise prospective depositors about import and quarantine regulations and the procedures that must be followed. Information may also be obtained from the Veterinary Services and/or the Plant Protection and Quarantine Biological Assessment Support Staff both at the US Department of Agriculture, Animal and Plant Health Inspection Service, Federal Center Building, Hyattsville, Maryland 20872, United States of America, and from the Department of Health and Human Services, Public Health Service, Office of Biosafety, Centers for Disease Control, Atlanta, Georgia 30333, United States of America.

Except in rare instances, the ATCC does not need to obtain import permits for microorganisms other than cell lines and viruses.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. Depositors are required to complete ATCC form BP/1 "Budapest Treaty Deposits" in all cases. For animal cell lines, hybridomas and viruses, the form referred to in (i), above, must also be completed, so that the ATCC may apply for an import permit. In the event of a later indication or amendment of the scientific description and/or proposed taxonomic designation, and a request for attestation that the ATCC has received such information, the depositor must complete ATCC form BP/7-8.

Official Notifications to the Depositor. The receipt and viability statement are issued on mandatory "international forms" BP/4 and 9 which are combined in form BP/4-9. Attestation of receipt of a later indication or amendment of the scientific description and/or proposed taxonomic designation is issued on form BP/7-8. Notification of release of a sample to a third party is issued on form BP/14. Standard forms are not used for other official notifications.

Unofficial Notifications to the Depositor. If requested, the ATCC will telephone or fax the date of deposit and accession number after a positive showing of viability, but before the official receipt is issued. A fee of \$10 is charged for this service. The ATCC similarly will telephone or telex the result of the viability test before the official viability statement is issued.

Supply of Information to a Patent Agent. The ATCC asks that the depositor supply the name, address, phone and fax number of the patent attorney or agent. The ATCC sends copies of the certificates and notifications to the depositor's attorney or agent.

(iii) Converting a Previous Deposit

Deposits made outside the provisions of the Budapest Treaty may be converted by the original depositor to Budapest Treaty deposits, whether or not they were originally deposited for patent purposes. However, any deposits previously made free of charge are subject on conversion to the storage fees normally levied for Budapest Treaty deposits. The administrative requirements for conversion are the same as those required for an original deposit made under the Treaty, except that requirements relating to import and/or quarantine procedures do not apply.

(iv) Making a New Deposit

New Deposit

In the event that the ATCC determines that a biological material is no longer viable, although originally found viable upon initial deposit, the depositor may replace the nonviable deposit with a new deposit. The deposit will retain its initial deposit number and date as long as (1) the replacement deposit is viable, (2) the ATCC receives the replacement deposit within three months of receipt by the depositor of the notification of nonviability, and (3) the ATCC receives a statement signed by the depositor alleging that the newly deposited biological is the same as that originally deposited. The only charges are for viability testing.

Supplemental Deposits

In the event that the ATCC determines that the deposit, although still viable, no longer retains the characteristics as originally thought, the depositor will be asked to provide a Supplemental Deposit. This deposit will obtain a new date and a new accession number. All the normal forms for deposit must be filled out and the regular fees for an original deposit apply.

2. Furnishing of Samples

(a) Requests for Samples

Generally, availability of the biological material is required only after the issuance of a pertinent patent. Prior to that time, the deposit need only be made available to a requesting party if (1) the Commissioner of the United States Patent and Trademark Office, in accordance with 35 U.S.C. paragraph 122, issues a decision to release such deposit; (2) the patent office of another country signatory to the Budapest Treaty issues such a decision to release the deposit to a particular requesting party; or (3) the original depositor requests in writing that the deposit be released to a particular requesting party. The ATCC will provide requesting parties with form BP/12 or request forms used by an individual industrial property office.

Notwithstanding any entitlement of third parties to receive samples under patent regulations, the ATCC will withhold samples of organisms that are subject to health and safety regulations until it has confirmed that the requesting party can comply with such

regulations. For organisms considered potentially very dangerous, the requesting party must sign an assurance of acceptance of responsibility. Also, in some cases a permit is required to work with certain material in the United States of America, and a requesting party in the United States of America must obtain such a permit before he can receive a sample. If a valid request is received from overseas for a sample of a microorganism that would require a permit to be worked with in the United States of America, the ATCC advises the requesting party to check the import requirements of his own country. If the ATCC knows that a country requires an import permit for a microorganism (even if the United States of America does not), it will so advise a requesting party in that country.

(b) Notification of the Depositor

The ATCC offers a notification service in which a depositor is notified on form BP/14 each time a sample of the deposit is furnished to a third party. For the fee relating to this service, see below under 3 (Schedule of Fees).

(c) Cataloguing of Budapest Treaty Deposits

If the depositor or a competent patent office instructs the ATCC to make samples of a microorganism available to anyone, that organism is listed in the next published ATCC catalog.

3. Schedule of Fees

<u>Storage</u>	<u>US\$</u>
Thirty years of storage and notification of requesting parties (except multiple sequences and consortia):	\$1,100.00
Thirty years of storage and notification of requesting parties for multiple sequences: ³	\$1,200.00
Thirty years of storage and notification of requesting parties for consortia:	\$1,200.00 or quoted price

³ Maximum of 10 sequences per deposit.

	<u>US\$</u>
<u>Viability Testing</u>	
Microorganisms (bacteria, fungi, yeasts, seeds):	\$150.00
Cell lines of hybridomas ⁴ :	\$300.00
Vectors, libraries, plasmids, purified DNA:	\$200.00 or quoted price
Consortia, embryos:	Quoted price
Plant tissue cultures:	\$300.00
Protozoa and algae (standard):	\$250.00
Animal viruses (depositor supplies cells):	\$400.00
Animal viruses (ATCC supplies cells):	\$500.00
Animal viruses (animal or equipment needed):	Quoted price
Plant viruses:	Quoted price

In some cases, the cost to perform a viability test will be a quoted price and may be higher than the prices listed below. In these cases, the depositor will be notified and asked to provide written authorization for ATCC to perform the viability test at the quoted price.

<u>All ATCC Cultures</u>	<u>US\$ per Item</u>
U.S. Non-Profit Institutes	\$95.00 to \$236.00
Foreign Non-Profit Institutions	\$95.00 ⁵ to \$236.00 ⁶
Other U.S. and Foreign Institutions	\$119.00 to \$295.00

Because of the diversity of ATCC holdings, and the requirements for complicated and varied culture media and growth conditions, the fees for ATCC cultures vary. Therefore, the current fees have been listed as a range representing all currently available ATCC cultures.

⁴ PCR-based mycoplasma testing required (including in viability fee).

⁵ Additional handling and processing: \$24.00 per item.

⁶ Additional handling and processing: \$59.00 per item.

Shipping charges—perishable or pathogenic materials which by their nature require special packaging, handling and/or shipping are shipped FOB origin, freight prepaid via carrier of ATCC's choice.

4. Guidance for Depositors

The ATCC publishes a brochure giving details of its requirements and practices for the deposit of cultures for patent purposes.

SECTION E: REQUIREMENTS OF INDUSTRIAL PROPERTY OFFICES
OF STATES PARTY TO THE BUDAPEST TREATY AND OF
INTERGOVERNMENTAL INDUSTRIAL PROPERTY ORGANIZATIONS

Introduction

(i) General

This section describes the statutory requirements and the practices of the industrial property offices of the States party to the Budapest Treaty and of the African Regional Industrial Property Organization (ARIPO) and European Patent Office (EPO) as regards the deposit of microorganisms for the purposes of patent procedure.

(ii) Information on Industrial Property Offices

The industrial property offices are listed by country in accordance with the two-letter country code as per WIPO Standard ST.3, followed by the African Regional Industrial Property Organization (ARIPO) and the European Patent Office, according to the following scheme: country, name of industrial property office, address, telephone, telex and telefax numbers, if any.

1. Requirements for Deposit

Information is given on the question whether the deposit with an international depositary authority of a microorganism which is the subject of a patent application, is obligatory in order to describe the invention adequately.

2. Time of Deposit

The time limit is indicated for depositing with an international depositary authority a microorganism which is the subject of a patent application.

3. Duration of Storage

Information is given on the length of time during which a microorganism deposited with an international depositary authority must be stored by the said authority.

4. Conditions for the Furnishing of Samples

(i) Time of Availability of Samples

Information is given when samples of deposited microorganisms should be available to any requesting party.

(ii) Restrictions Concerning the Furnishing of Samples

Information is given with respect to restrictions on the availability of samples of deposited microorganism.

AT – AUSTRIA

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Federal Ministry for Transport, Innovation and Technology
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Telex: 1 36847 OEPA A
Telefax: (431) 53 424 - 520
Internet home page: <http://www.patent.bmwa.gv.at>

1. Requirements for Deposit

The deposit of a microorganism with an international depositary authority under the Budapest Treaty is required if an invention relates to a microorganism, a microbiological process or a product obtained by such process and if the microorganism is not accessible to the public and cannot be described in the application in such a manner as to enable the invention to be carried out by a person skilled in the art.

The application as filed must contain the authoritative data as available to the applicant concerning the features of the microorganism.

The name of the international depositary authority and the number of the deposit must be notified to the Patent Office before the decision to publish the patent application for opposition purposes is taken.

(Patent Law of 1970, as amended to 1986, Section 87a(2) 2 and 3)

2. Time of Deposit

A culture of the microorganism must be deposited with an international depositary authority not later than the filing date of the patent application.

(Patent Law, Section 87a(2)1.)

3. Duration of Storage

No provision.

4. Conditions for the Furnishing of Samples

No provision.

AU – AUSTRALIA

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IP Australia
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WODEN, ACT. 2606
Australia

Telephone: (612) 6283 2211
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1. Requirements for Deposit

The deposit of a culture of a microorganism is required if the invention involves the use, modification or cultivation of a microorganism which is not reasonably available to a person skilled in the art and if, without a sample of such microorganism, such person could not reasonably be expected to be able to perform the invention.

(Patents Act 1990, Sections 6, 41(1) and (a); Regulation 1.5(1) and (a).)

2. Time of Deposit

A culture of a microorganism must be deposited on or before the date of lodgment of the specification.

(Patents Act, Section 6(a).)

3. Duration of Storage

A deposited microorganism shall be stored for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism was received by the international depositary authority and, in any case, for a period of at least 30 years after the date of the deposit.

(Patents Act, Section 6(d); Budapest Treaty Rule 9.1.)

4. Conditions for the Furnishing of Samples

(i) Time of Availability of Samples

Samples of deposited microorganisms may be made available to a requesting party provided the specification lodged in respect of the patent application or patent is open to public inspection.

(Patents Regulations, Regulation 1.5(a) and 3.25(4)(a).)

(ii) Restrictions Concerning the Furnishing of Samples

A requesting party must give an undertaking:

- (a) not to make the microorganism, or any culture derived from the microorganism, available to any other person, and
- (b) to use the microorganism only for experimental purposes, during specified periods.

(Patents Regulations, Regulation 3.25(4)(c), Form P/00/068.)

The specified periods are:

- (a) any period when the patent application or patent is in force;
- (b) if the patent application lapses under Section 142(a)(d) of the Patents Act—the period of six months after the application so lapses; and
- (c) if the patent (or patent granted in accordance with the application) ceases under Section 143 of the Patents Act—the period of six months after that cessation.

The Commissioner may also require, before granting the certification referred to in Rule 11.3(a) of the Budapest Treaty Regulations, that a requesting party comply with such conditions as are reasonable, including a condition that the requestor give security for damages for any breach of the undertaking.

(Patents Regulations, Regulation 3.25(a).)

BE – BELGIUM

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Ministry of Economic Affairs
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Internet home page: <http://www.european-patent-office.org>

1. Requirements for Deposit

If an invention concerns the use of a microorganism which is not available to the public, a culture of the microorganism must be deposited with a depositary authority.

(Patent Law of 1984, Section 17.1.)

The description of the patent application must contain the information concerning the microorganism available to the applicant, the name of the depositary authority and the number of the deposit of the microorganism.

(Royal Decree of 1986, Section 10.1.)

The name of the depositary authority and the number of the deposit must be communicated to the Industrial Property Office within 16 months after the filing date of the patent application or, where a priority is claimed, the priority date and until the date of the request for the early grant of a patent.

(Royal Decree, Section 10.3.)

2. Time of Deposit

The deposit must be made not later than the date of filing the patent application.

(Royal Decree, Section 10.1(2).)

3. Duration of Storage

No provision.

4. Conditions for the Furnishing of Samples

(i) Time of Availability of Samples

A sample of a deposited microorganism becomes available to any requesting party as from the date of the issue of the patent upon request to the Industrial Property Office.

(Royal Decree, Section 10.5.)

(ii) Restrictions Concerning the Furnishing of Samples

The requesting party must undertake vis-à-vis the patentee not to communicate to third parties the deposited culture or any derived culture as long as the patent is in force.

(Royal Decree, Section 10.5.)

BG – BULGARIA

Patent Office of the Republic of Bulgaria
52B, Dr. G.M. Dimitrov Blvd.
1113 SOFIA
Bulgaria

Telephone: (359-2) 710 152
Telex: 23412 BPO BG
Telefax: (359-2) 708 325

1. Requirements for Deposit

If an invention involves a strain of a microorganism, it should be deposited with the Bulgarian depositary institution or with an international depositary authority with a separate deposit number.

(Instructions for Drafting and Examining Applications for Inventions by the Chairman of the State Committee for Science and Technological Progress of August 4, 1969, Sections 2.20, 3.11 and 7.3.)

Under the practice of the Bulgarian industrial property office, a culture of a microorganism should be deposited with the National Bank for Industrial Microorganisms and Cell Cultures (NBIMCC), if the microorganism is not available to the public or the invention involving that microorganism cannot be described in such a manner as to enable the invention to be carried out by a person skilled in the art.

The applicant should file a copy of the document proving the deposit of the microorganisms issued by the depositary authority at the time of filing the application. The applicant must indicate the deposit number of the microorganism and the name of the depositary authority with which such microorganism has been deposited.

2. Time of Deposit

Under the existing practice, the deposit must be made not later than the filing date of the application or, if priority is claimed, the priority date.

3. Duration of Storage

Under the existing practice, the duration of storage is unlimited.

4. Conditions for the Furnishing of Samples

(i) Time of Availability of Samples

Under the existing practice, the deposited culture should be available to the public as from the date of the grant of the relevant title of protection.

(ii) Restrictions Concerning the Furnishing of Samples

Under the existing practice, samples of the deposited microorganism should be furnished only to the requesting party who undertakes vis-à-vis the patentee to use the samples for experimental purposes only and not to make the samples available to any third party.

CA – CANADA

Canadian Intellectual Property Office (CIPO)
Place du Portage
50 Victoria Street
HULL Québec K1A 0C9
Canada

Telephone: (1-819) 997 1725
Telefax: (1 819) 953 9538 (PCT Office)
E-mail: cipo.contact@ic.gc.ca
Internet home page: <http://cipo.gc.ca>

1. Requirements for Deposit

Where a specification in a patent application, or in a patent issued on the basis of such an application, refers to a deposit of biological material, the deposit of the biological material is considered to be in accordance with the Patent Regulations if it has been made by the applicant with an international depositary authority. The applicant must inform the Commissioner of Patents of the name of the international depositary authority, the date of the original deposit and the accession number given by the international depositary authority to the deposit. The said information must be included in the description of the patent application and must be provided before the application is open to public inspection.

(Patent Rules 1996¹, Sections 103 and 104)

2. Time of Deposit

The deposit of the biological material must be made with an international depositary authority on or before the filing date of the patent application.

(Patent Rules, Section 104)

3. Duration of Storage

No provision.

¹ The Patent Rules 1996, also contain provisions concerning *Applications Filed in the Period Beginning on October 1, 1989 and Ending on October 1, 1996* (Sections 159 to 166) and *Applications Filed Before October 1, 1989* (Sections 183 to 187).

4. Conditions for the Furnishing of Samples

(i) Time of Availability of Samples

Before the patent application is open to public inspection, the applicant may file a notice with the Commissioner of Patents stating the applicant's wish that, until either a patent has been issued on the basis of the application, or the application is refused, or is abandoned and no longer subject to reinstatement, or is withdrawn, a sample of the deposited biological material be furnished only to an independent expert nominated by the Commissioner.

(Patent Rules, Subsection 104(4))

The Intellectual Property Office publishes in the *Canadian Patent Office Record* a form for making a request for the furnishing of a sample of the deposit.

(Patent Rules, Subsection 107(1)).

Where the specification in a Canadian patent or in a patent application filed in Canada that is open to public inspection refers to a deposit of biological material by the applicant, and where a person files with the Commissioner of Patents a request made on the form referred to in Subsection 107(1), the Commissioner makes the certification referred to in Rule 11.3(a) of the Regulations under the Budapest Treaty in respect of that person and sends a copy of the request, together with the certification, to the person who filed the request.

(Patent Rules, Subsections 107(2) and (3))

(ii) Restrictions Concerning the Furnishing of Samples

Until either a patent has been issued on the basis of the patent application or the application is refused, or is abandoned and no longer subject to reinstatement, or is withdrawn, the Commissioner of Patents does not make the certification referred to in subsection 107(2) in respect of a person unless the Commissioner has received an undertaking by that person to the applicant:

- not to make any sample of biological material furnished by the international depositary authority or any culture derived from such sample available to any other person before either a patent is issued on the basis of the application or the application is refused, or is abandoned and no longer subject to reinstatement, or is withdrawn; and

- to use the sample of biological material furnished by the international depositary authority and any culture derived from such sample only for the purpose of experiments that relate to the subject-matter of the application until either a patent is issued on the basis of the application or the application is refused, or is abandoned and no longer subject to reinstatement, or is withdrawn.

(Patent Rules, Section 108)

Where a notice has been filed with the Commissioner of Patents pursuant to subsection 104(4) in respect of a patent application, the Commissioner, upon request of any person that an independent expert be nominated and with the agreement of the applicant, nominates, within a reasonable time, a person as an independent expert for the purposes of that application.

If no agreement can be reached on the nomination of an independent expert within a reasonable time after the request is made, the notice of the applicant referred to in subsection 104(4) is deemed never to have been filed.

(Patent Rules, Section 109)

Where a notice has been filed with the Commissioner of Patents pursuant to subsection 104(4) in respect of a patent application, until a patent is issued on the basis of the application or the application is refused, or is abandoned and no longer subject to reinstatement, or is withdrawn, a request pursuant to section 107 may only be filed by an independent expert nominated by the Commissioner in accordance with section 109.

Where the Commissioner of Patents makes a certification pursuant to subsection 107(2) in respect of an independent expert nominated by the Commissioner, a copy of the request, together with the certification, is sent to the applicant and to the person who requested the nomination of the independent expert.

(Patent Rules, Section 110).

CH – SWITZERLAND

Swiss Federal Intellectual Property Office
Einsteinstrasse 2
CH-3003 BERNE
Switzerland

Telephone: (41-31) 325 25 25
Telefax: (41-31) 325 25 26
Internet home page: <http://www.ige.ch>

1. Requirements for Deposit

Where an invention concerning a microbiological process or a product obtained by such a process entails the use or production of a microorganism to which the public does not have access and which cannot be described in the technical documents in such a way as to enable a person skilled in the art to carry out the invention, the applicant must supplement the description of the invention by reference in it to the deposit of a culture of the microorganism.

(Ordinance on Patents for Inventions of 1977, as amended to 1987, (“Ordinance on Patents”) Section 27(1).)

2. Time of Deposit

The culture must be deposited not later than the filing date of the patent application. The reference may be furnished within 16 months from the date of filing of the patent application or, if priority is claimed, from the priority date.

(Ordinance on Patents, Section 27(2) and (5).)

3. Duration of Storage

The provisions of Rule 9 of the Regulations under the Budapest Treaty are applied and the duration of storage is a minimum of 30 years.

4. Conditions for the Furnishing of Samples

(i) Time of Availability of Samples

No provision.

(ii) Restrictions Concerning the Furnishing of Samples

The release of samples of a culture to third parties may be made subject to the condition that those third parties communicate to the institution possessing the culture collection their names and addresses for the information of the depositor and that they undertake:

(a) not to afford other persons access to the deposited culture or to a culture derived therefrom;

(b) not to use it outside the scope of the Law;

(c) to prove, in the event of litigation, that they have not failed to honor their undertakings under items (a) and (b).

(Ordinance on Patents, Section 27(6).)

CN – CHINA

Chinese Patent Office (CPO)
Haidian District
P.O. Box 8020
100088 BEIJING
China

Telephone: (86-10) 6 209 3677
Telex: 22541 POPRC CN
Telefax: (86-10) 6 201 9615

1. Requirements for Deposit

Where an application for a patent for invention concerns a new microorganism, a microbiological process or a product thereof and involves the use of a microorganism which is not available to the public, the applicant must deposit a sample of the microorganism with a depositary institution designed by the Patent Office or with an international depositary authority under the Budapest Treaty.

The applicant must give, in the application document, relevant information on the characteristics of the microorganism.

Where the application relates to the deposit of the microorganism, the applicant must indicate in the request and in the description the scientific name (with its Latin name) and the name of the depositary institution, the date on which the sample of the microorganism was deposited and the accession number of the deposit. Where the said information is not supplied at the time of filing, it must be supplied within three months from the date of filing. If it is not supplied after the expiration of the time limit, the sample of the microorganism shall be deemed not to have been deposited.

(Implementing Regulations of the Patent Law of 1992, Rule 25; the Budapest Treaty, Art. 3(1)(a)).

2. Time of Deposit

The deposit of a sample of the microorganism with a depositary institution designated by the Patent Office must be made before the date of filing, or, at the latest, on the date of filing. The applicant must submit, at the time of filing, or at the latest, within three months from the filing date, a receipt of deposit and the viability proof from the depositary institution. Where the said information is not submitted within the specified time limit, the sample of the microorganism shall be deemed not to have been deposited.

(Implementing Regulations, Rule 25(1).)

3. Duration of Storage

The microorganism must be stored for a period of at least 30 years from the date of deposit.

(Regulations on the Deposit of Microorganisms for the Purposes of Patent Procedure, Section 7.)

4. Conditions for the Furnishing of Samples

After the publication of an application for a patent for invention relating to a microorganism, any entity or individual which or who intends to make use of the microorganism mentioned in the application for the purpose of experiment shall make a request to the Patent Office containing the following:

1. the name and address of the entity or individual making the request;
2. an undertaking not to make the microorganism available to any other person;
3. an undertaking to use the microorganism for experimental purpose only before the grant of the patent right.

(Implementing Regulations, Rule 26.)

CU – CUBA

Cuban Industrial Property Office (OCPI)
Picota No. 15 entre Luz y Acosta
1, La Habana Vieja
LA HABANA 10100
Cuba

Telephone: (53-7) 61 0185; 62 9771; 62 4379; 62 3602
Telex: 511290 acp.cu
Telefax: (53-7) 33 5610; 33 8237

1. Requirements for Deposit

Patent applications involving a microorganism must be accompanied by a document proving the deposit of the microorganism.

(Methodology for the Elaboration of Application Documents for the Protection of Inventions.)

2. Time of Deposit

At the time of filing the patent application or three months thereafter.

(Methodology for the Elaboration of Application Documents for the Protection of Inventions.)

3. Duration of Storage

No provision.

4. Conditions for the Furnishing of Samples

No provision.

CZ – CZECH REPUBLIC

Industrial Property Office of the Czech Republic
Antonína Cermáka 2a
160 68 PRAGUE 6
Czech Republic

Telephone: (4202) 24 31 1555

Telefax: (4202) 243 24 718

E-mail: posta@upv.cz

1. Requirements for Deposit

The invention must be disclosed in the application for an invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. Where the invention concerns an industrial microorganism for the purposes of production, the microorganism must be kept in a public collection as from the date on which the applicant's priority right begins.

(Law on Inventions, Industrial Designs and Rationalization Proposals No. 527 of November 27, 1990, Section 26(2).)

In accordance with the practice, the applicant must attach to the patent application proof that the microorganism has been deposited.

2. Time of Deposit

In accordance with the practice, the deposit of the microorganism must be made not later than the date of filing of the patent application (see 1. above).

3. Duration of Storage

No provision.

4. Conditions for the Furnishing of Samples

No provision.

DE – GERMANY

German Patent and Trade Mark Office
Zweibrückenstrasse 12
D-80297 MUNICH

Gitschinerstr. 97
D-10969 BERLIN

Goethestr. 1
D-07743 JENA

Telephone: (4989) 21 95 0 (Munich)
(4930) 25 992 0 (Berlin)
(4936 41) 40 54 (Jena)
Telefax: (49-89) 2195-2221 (Munich)
(4930) 25 992 404 (Berlin)
(4936 41) 40 556 90 (Jena)

Internet home page: <http://www.patent-und-markenamt.de>

1. Requirements for Deposit

The culture of a microorganism should be deposited with the depositary institution if an invention involves that microorganism, and such invention cannot be described in such a manner as to enable a person skilled in the art to carry out the invention.

(Guidelines for the Examination Procedure of 1995, paragraph 4.2. (Applications Concerning Microorganisms))

2. Time of Deposit

The deposit must be made not later than the date of filing the patent application.

(Examination Guidelines, paragraph 4.2.2.1.)

3. Duration of Storage

The duration of storage of deposited microorganisms is a minimum of 30 years if the deposit is made under the provisions of the Budapest Treaty.

Notwithstanding the provisions of the Budapest Treaty, there is also the possibility of making a deposit in accordance with the principles established by the Federal Court of Justice [Bundesgerichtshof] in its Bäckerhefe (baker's yeast) decision (Blatt für Patent-, Muster- und Zeichenwesen 1975, p. 171). The prescribed duration of storage shall then be at least 25 years from the date of filing.

(Examination Guidelines, paragraph 4.2.2.3.)

4. Conditions for the Furnishing of Samples

(i) Time of Availability of Samples

When making a deposit according to the Budapest Treaty, samples of the deposited microorganism shall be available from the date of publication of the application under the conditions provided for in Rule 11 of the Regulations under the Budapest Treaty. When making a deposit in accordance with the principles established by the Federal Court of Justice and the Federal Patent Court, in addition a declaration of availability for release is required, which shall be furnished to the depository institution not later than on the date of filing (Bundespatentgericht Blatt für Patent-, Muster- und Zeichenwesen 1987, p. 402).

(ii) Restrictions Concerning the Furnishing of Samples

Following the decision of the Federal Supreme Court in the Bäckerhefe case (1975), requesting parties may be obliged not to pass the released samples to third parties and not to transfer them outside the territory of the jurisdiction of the Patent Law of Germany.

DK – DENMARK

Danish Patent Office
Ministry of Business and Industry
Helgeshøj Allé 81
DK-2630 TAASTRUP
Denmark

Telephone: (45) 4350 8000
Telex: 16046 DPO DK
Telefax: (45) 4350 8001
Internet home page: [http:// www.dkpto.dk](http://www.dkpto.dk)

1. Requirements for Deposit

A culture of a microorganism must be deposited if the carrying out of the invention involves the use of a microorganism which is neither available to the public nor describable in the patent application in such a manner as to enable a person skilled in the art to carry out the invention.

(Patents Act of 1967 as amended to 1984, Section 8a(1).)

2. Time of Deposit

The deposit of a microorganism must be made not later than the date of filing of the patent application.

(Patents Act, Section 8a(1).)

3. Duration of Storage

Under the patent practice of Denmark, the duration of storage of a deposited microorganism is a minimum of 30 years.

4. Conditions for the Furnishing of Samples

(i) Time of Availability of Samples

A culture of a microorganism becomes available from the date on which the application is made available to the public.

(Patents Act, Section 22(6).)

(ii) Restrictions Concerning the Furnishing of Samples

The patentee may request that a sample of the deposited microorganism shall only be available to an expert in the art until the patent application has been laid open to public inspection or has been finally decided upon without having been laid open to public inspection. An expert is a person whose name is included in a list published in the Patent Office for the purpose of handling samples of deposited microorganisms.

(Patents Act, Section 22(7); Ministerial Order Concerning Patent Applications of 1985, Section 25(b).)

The request for the furnishing of a sample must be filed in writing with the Patent Office and must contain a declaration of compliance with the following restrictions on the use of the sample:

(a) If the request is made before the patent application referring to the deposit of a microorganism has been finally decided upon, the requesting party must undertake vis-à-vis the applicant to use the sample of the microorganism deposited for experimental purposes only, until the patent application is finally decided upon, and not to make the sample available to any third party within the same period or, if a patent is granted, before the expiry of the patent.

As far as cultures are concerned which are derived from the sample and still exhibit those characteristics of the deposited culture which are essential to carrying out the invention, the person requesting the sample shall accept the same obligations as those applying to the sample.

(Ministerial Order, Section 25(a).)

(b) If the request is made after a patent referring to the deposit of a microorganism is granted, the requesting party shall undertake vis-à-vis the owner of the patent not to make the sample of the deposited microorganism available to any third party before the expiry of the patent.

(Ministerial Order, Section 25(a).)

If a sample of the deposited microorganism must be furnished to an expert, the expert shall make the declaration referred to above.

(Ministerial Order, Section 25(b)(3).)

EE – ESTONIA

Estonian Patent Office
Toompuiestee 7
0100 TALLINN
Estonia

Telephone: (372) 6 277 900
Telefax: (372) 645 13 42

1. Requirements for Deposit

If the subject of the invention is a microorganism or if the invention implies the use of a new microorganism, the patent applicant must submit the document proving the deposit of the microorganism.

(Patent Law of 1994, Article 19(1)(v).)

2. Time of Deposit

The document proving the deposit of the microorganism must be filed together with the patent application.

(Patent Law, *ibid.*)

3. Duration of Storage

No provision.

4. Conditions for the Furnishing of Samples

No provision.

ES – SPAIN

Spanish Patent and Trademark Office
Ministry of Industry, Trade and Tourism
Panamá 1
28071 MADRID
Spain

Telephone: (34-1) 349 55 32
Telefax: (34-1) 45 53 04
Internet home page: <http://www.oepm.es>

1. Requirements for Deposit

If an invention refers to a microbiological process for which the microorganism is not available to the public, the applicant shall deposit a culture of the microorganism with an authorized institution.

(Law on Patents of 1986, Section 25(2)(b).)

2. Time of Deposit

The deposit must be made not later than the date of filing the patent application.

(Law on Patents, Section 25(2)(b).)

3. Duration of Storage

No provision.

4. Conditions for the Furnishing of Samples

(i) Time of Availability of Samples

A sample of a deposited microorganism becomes available to the public as from the date of publication of the patent application.

(Law on Patents, Section 25(2)(c).)

(ii) Restrictions Concerning the Furnishing of Samples

In accordance with Section 25(2)(c) of the Law, the culture of the deposited microorganism must be available as from the date of publication of the patent application to all persons making a request and, prior to that date, to any person entitled to consult the application file, in accordance with the provisions of Section 44(2) of the Law.

Access is provided by furnishing a sample of the requested microorganism on condition that the person requesting access to the culture undertakes vis-à-vis the applicant or owner of the patent:

(a) not to communicate to third parties the culture that is the subject matter of the patent or a culture derived from it before the patent application has been rejected or withdrawn or deemed to have been withdrawn or the patent has expired;

(b) not to use the culture that is the subject matter of the patent or a culture derived from it other than for experimental purposes up to the date on which the patent application has been refused or withdrawn or deemed to have been withdrawn or up to the date of publication of the grant of the patent.

Where, for whatever reason, the authorized institution is unable to furnish samples of the deposited microorganism, the provisions of the Budapest Treaty and its Regulations apply.

(Regulations to the Law on Patents of 1986, Rule 6.)

FI – FINLAND

National Board of Patents and Registration of Finland
P.O. Box 1160
00161 HELSINKI
Finland

Telephone: (358-9) 6939 500
Telefax: (358-9) 6939 5233
Internet home page: <http://www.prh.fi>

1. Requirements for Deposit

A culture of a microorganism must be deposited if the carrying out of the invention involves the use of a microorganism which is neither available to the public nor describable in the patent application in such a manner as to enable a person skilled in the art to carry out the invention.

(Patent Law of 1967, as amended to 1985, Section 8a.)

The deposit shall be made with an international depositary authority under the Budapest Treaty.

(Patent Decree No. 505 of 1985, Section 17(a).)

Within 16 months from the filing date of the patent application or, where priority is claimed, the priority date, the applicant must inform the National Board of Patents and Registration in writing of the name of the depositary authority, the date on which the deposit was made and the number given to the deposit. In case of a PCT application, this information may be filed by the applicant with the International Bureau.

In case the applicant makes a request that the patent application be made available to the public earlier than 18 months from the date of filing or, if priority is claimed, from the priority date, the above-mentioned information should be submitted, at the latest, together with the said request.

(Decree No. 505, Section 17(b).)

2. Time of Deposit

The deposit of the microorganisms must be made not later than the date of filing of the patent application.

(Patent Law, Section 8a.)

3. Duration of Storage

The deposit must be made according to the Budapest Treaty (Decree No. 505, Section 17(a)). Therefore, the duration of the storage of microorganisms is the same as in Rule 9 of the Budapest Treaty.

4. Conditions for the Furnishing of Samples

(i) Time of Availability of Samples

Samples become available when the application is laid open to the public, that is to say, 18 months from the filing date or, if priority is claimed, from the priority date, except when the applicant requests an earlier disclosure of its application.

If the applicant so requests, samples of a deposited microorganism are furnished only to an expert until the patent application has been laid open to public inspection or has been finally decided on without being laid open to public inspection. Such a request must be made within 16 months from the filing date of the application or, if priority is claimed, from the date from which priority is claimed. In case of a PCT application the request may be filed by the applicant with the International Bureau.

(Patent Law, Section 22; Decree No. 505, Section 25(b).)

(ii) Restrictions Concerning the Furnishing of Samples

The applicant may request that samples of the deposited microorganism shall only be available to an expert in the art until the patent application has been laid open to public inspection or has been finally decided upon without having been laid open to public inspection. An expert is a person who has declared himself willing to act as an expert according to the Finnish Patent Law and whose name is included in a list of experts published by the National Board of Patents and Registration. The expert can also be any person approved by the applicant in the individual case.

(Patent Law, Section 22; Decree No. 505, Section 25(b).)

The request for the furnishing of a sample must be filed in writing with the National Board of Patents and Registration and must contain a declaration of compliance with the following restrictions on the use of the sample:

(a) If the request is made before the patent application referring to the deposit of a microorganism has been finally decided upon, the requesting party must undertake vis-à-vis the applicant to use the sample of the microorganism deposited for experimental purposes only, until the patent application is finally decided upon, and not to make the sample available to any third party within the same period or, if a patent is granted, before the expiry of the patent.

(b) If the request is made after a patent referring to the deposit of a microorganism is granted, the requesting party shall undertake vis-à-vis the owner of the patent not to make the sample of the deposited microorganism available to any third party before the expiry of the patent.

(Decree No. 505, Section 25(a).)

If a sample of the deposited microorganism may only be issued to an expert, the expert shall make the declaration referred to above.

(Decree No. 505, Section 25(b).)

FR – FRANCE

National Institute of Industrial Property
26bis, rue de Saint-Pétersbourg
75800 PARIS Cédex 08
France

Telephone: (33-1) 53 04 53 04
Telex: 290 368 INPI, Paris
Telefax: (33-1) 43 87 74 68
Internet home page: <http://www.inpi.fr>

1. Requirements for Deposit

If an invention concerns the use of a microorganism which is not available to the public, a sample of the microorganism must be deposited with an authorized institution.

(Law No. 92-597 of 1992 on the Intellectual Property Code, as amended in 1994, Article L. 612-5.)

The description of the patent application must indicate:

- (a) the information available to the applicant on the characteristics of the microorganism;
- (b) the authorized institution with which a sample of the microorganism has been deposited, and number of the deposit. This information may be furnished within 16 months from the filing date of the patent application or, if priority is claimed, from the date of priority.

(Decree No. 95-385 of 1995, Article R. 612-14.)-

2. Time of Deposit

The deposit of a microorganism must be made not later than the date of filing the patent application.

(Decree of 1995, Article R. 612-14.)

3. Duration of Storage

The duration of storage of deposited microorganisms is a minimum of 30 years.

4. Conditions for the Furnishing of Samples

(i) Time of Availability of Samples

Any person may ask to have access to a deposited microorganism, either as from the day of publication of the patent application (which takes place 18 months from the filing date or, if a priority is claimed, from the date of priority), or before that date if a copy of the patent application has been conveyed to him.

(Decree of 1995, Article R. 612-42.)

(ii) Restrictions Concerning the Furnishing of Samples

The request must be filed in writing with the National Institute of Industrial Property. It must contain the name and address of the requesting party and an undertaking on his part:

(a) not to communicate the culture or a culture derived therefrom to any person unless the patent application has been refused or withdrawn or the patent has ceased to produce its effects;

(b) to use the culture or a culture derived therefrom for experimental purposes, except where the patent application has been refused or withdrawn, or where the fact of grant has been published. This undertaking however, will not prevent the use of the sample by virtue of a compulsory or ex officio license.

The applicant for the patent may indicate, by a written declaration made before the completion of the technical preparation for the publication of the patent application that, until the publication of the grant of the patent, the withdrawal or refusal of the application, the deposited culture shall only be accessible to an expert designated by the applicant.

The conditions of acceding to the culture and the undertaking by the expert are those mentioned above for the requesting party.

(Decree of 1995, Article R. 612-42 and 43.)

GB – UNITED KINGDOM

The Patent Office
Department of Trade and Industry
Concept House
Tredegar Park
Cardiff Road
NEWPORT, South Wales NP9 1RH
United Kingdom

Telephone: (44-1633) 81 4000

Telefax: (44-1633) 81 4444

Internet home page: <http://www.patent.gov.uk>

1. Requirements for Deposit

The deposit of a microorganism shall be made if an invention requires for its performance the use of a microorganism which is not available to the public at the date of filing of the patent application and which cannot be described in such a manner as to enable the invention to be performed by a person skilled in the art. The name of the depositary institution, the date when the culture was deposited and the accession number of the deposit should be given in the specification of the application. Such information may be added to the application

- before the end of the period of 16 months after the declared priority date or, where there is no declared priority date, the date of filing of the application;
- where, on request by the applicant, the Comptroller publishes the application before the end of the period prescribed for the purposes of Section 16(1), before the date of the request;
- where in accordance with Section 118(4) the Comptroller notifies the applicant that a request has been made for information and inspection of documents under Section 118(1), before the end of one month after the Comptroller has sent to the applicant notification of his receipt of the request.

(Patents Rules 1990, Rule 17, Schedule 2, paragraph 1.)

2. Time of Deposit

The deposit must be made not later than the date of filing the patent application.

(Patents Rules 1990, Rule 17, Schedule 2, paragraph 1(2)(a)(i).)

3. Duration of Storage

No provision.

4. Conditions for the Furnishing of Samples

(i) Time of Availability of Samples

A culture of a deposited microorganism is available upon request before publication of the relevant patent application to a person to whom Section 118(4) applies and who has made a request under Section 118(1) and is available upon such publication to any person.

(Patent Rules 1990, Rule 17, Schedule 2, paragraph 2(1).)

(ii) Restrictions Concerning the Furnishing of Samples

A request authorizing the furnishing of samples shall comprise on the part of the person making the request an undertaking for the benefit of the patent applicant or the owner of the patent:

(a) not to make the culture, or any culture derived from it, available to any other person; and

(b) not to use the culture, or any culture derived from it, otherwise than for experimental purposes relating to the subject matter of the invention.

Both undertakings shall have effect until the patent application has been withdrawn, has been taken to be withdrawn, has been treated as having been withdrawn, has been refused or is treated as having been refused (including any further period allowed under Rule 100 or Rule 110(1) or (4) but excluding, where an application is reinstated under either of those rules, the period before it is reinstated).

Where the patent is granted, the undertaking in subparagraph (a), above, shall also have effect during the validity of the patent and during the period of six months referred to in Section 25(4).

The undertaking set out in subparagraph (b), above, shall not have effect after the date of publication in the Official Journal (Patents) of a notice that the patent has been granted.

The request for the furnishing of samples should be made on Patents Form 8/77.

(Patents Rules 1990, Rule 17, Schedule 2, paragraph 2(3).)

Before the preparations for publication of a patent application under Section 16 have been completed, the applicant may give notice to the Comptroller on Patents Form 8A/77 of his intention that a sample of the microorganism should be furnished only to an expert. Where this has been done, the Comptroller will publish with the application a notice to this

effect and persons requesting samples must nominate an expert who must have given undertakings in accordance with subparagraphs (a) and (b), above. The request for the furnishing of samples in these circumstances should be made on Patents Form 8B/77. The Comptroller shall specify the period within which the patent applicant may object to the furnishing of a sample of the microorganism to the particular expert nominated.

In the case of an international application, the applicants notice that a sample should be furnished only to an expert should be given in writing to the International Bureau under Rule 13bis.3 of the Regulations under the Patent Cooperation Treaty before technical preparations for international publication are complete.

(Patent Rules 1990, Rule 17, Schedule 2, paragraph 3(1) and (4).)

GR – GREECE

Industrial Property Organisation (OBI)
5, Pandanassis St.
Paradissos Amaroussiou
151 25 ATHENS
Greece

Telephone: (30-1) 618 35 48
Telefax: (30-1) 681 92 31

1. Requirements for Deposit

No provision.

2. Time of Deposit

No provision.

3. Duration of Storage

No provision.

4. Conditions for the Furnishing of Samples

No provision.

HR – CROATIA

State Intellectual Property Office of the Republic of Croatia
Ulica grada Vukovara 78
HR-10000 Zagreb

Telephone: (3851) 61 06 436
Telefax: (3851) 61 12 017
Internet home page: <http://pubwww.srce.hr/patent>

1. Requirements for Deposit

No provision.

2. Time of Deposit

No provision.

3. Duration of Storage

No provision.

4. Conditions for the Furnishing of Samples

No provision.

HU – HUNGARY

Hungarian Patent Office
P.O. Box 552
H-1370 BUDAPEST
Hungary

Telephone: (36-1) 331 67 80
Telex: 224700 OTH H
Telefax: (36-1) 331 65 96; 331 25 96
Internet home page: <http://www.hpo.hu>

1. Requirements for Deposit

If an invention involving the use of a microorganism which is not available to the public cannot be disclosed in the patent application, as required by Article 60(1), a certificate shall be filed attesting to the fact that a culture of the microorganism has been deposited under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure.

(Law No. XXXIII of 1995 on the Protection of Inventions by Patents.)

2. Time of Deposit

If the culture of a microorganism is deposited after the filing of the patent application, the date of deposit shall be regarded as the date of filing.

The certificate of deposit may be submitted within a period of four months after the date of filing.

(Law No. XXXIII of 1995 on the Protection of Inventions by Patents.)

3. Duration of Storage

The NCAIM stores microorganisms for the duration of the patent protection in Hungary (20 years from the filing date in Hungary).

(Decree of the Minister of Agriculture and Food, No. 15/1986 of September 17, 1986, Sections 4 and 5.)

The duration of storage, when the NCAIM is acting as a depositary authority under the Budapest Treaty, is determined by the relevant rules of the Treaty and of the Regulations under the Treaty.

4. Conditions for the Furnishing of Samples

(i) Time of Availability of Samples

The deposited culture shall be made available by the depositary institution by furnishing samples to any person after the date of publication of the patent application and to any person having the right to inspect the files under the provisions of Article 53(1) prior to that date.

(Law No. XXXIII of 1995 on the Protection of Inventions by Patents.)

(ii) Restrictions Concerning the Furnishing of Samples

The person to whom a sample of the microorganisms has been furnished may not make the deposited culture or any culture derived therefrom available to any third party before the termination of the patent grant procedure or before the lapse of patent protection and, with the exception of a holder of a compulsory license, he may use the deposited culture only for experimental purposes. A derived culture is deemed to be any culture of the microorganism which still has those characteristics of the deposited culture which are essential to carry out the invention.

(Law No. XXXIII of 1995 on the Protection of Inventions by Patents.)

IE – IRELAND

Patents Office
Department of Enterprise, Trade and Employment
Governments Buildings
Hebron Road
Kilkenny
Ireland

Telephone: (353 56) 20111
Telefax: (353 56) 20100
Internet home page: <http://www.irlgov.ie/entemp>

1. Requirements for Deposit

No provision.

2. Time of Deposit

No provision.

3. Duration of Storage

No provision.

4. Conditions for the Furnishing of Samples

No provision.

IL – ISRAEL

Patent Office
Ministry of Justice
Lev Hagiva Building
11, Rehov Beit Hadehus
Givat Shaul
P. O. Box 34255
91341 JERUSALEM
Israel

Telephone: (972-2) 5316 666
Telefax: (972-2) 5316 590

Legislation on the deposit of microorganisms for the purposes of the Budapest Treaty
is under preparation

IS – ICELAND

Icelandic Patent Office
Lindargötu 9
150 REYKJAVIK
Iceland

Telephone: (354) 560 9450
Telefax: (354) 562 9434
Internet home page: <http://www.els.stjr.is/>

1. Requirements for Deposit

If in the carrying out of an invention, a microorganism is to be used which is neither available to the public nor can be described in the application documents so as to enable a person skilled in the art to carry out the invention with the guidance thereof, a culture of the organism shall be deposited with an institution which is an international depositary authority under the Budapest Treaty.

(Patent Act, 1991, as amended in 1993, Section 8(6), and Regulation Concerning Patent Applications, 1991, Section 17a.)

2. Time of Deposit

A culture of the microorganism must be deposited not later than the date of filing of the patent application.

(Patent Act, Section 8(6).)

If an applicant has deposited a culture of a microorganism, he must within 16 months from the date of filing or, if priority is claimed, from the priority date, inform the Patent Office in writing of the name of the institution where the deposit has been made and which deposit number the institution has allotted the culture. In the case of international applications, the World Intellectual Property Organization shall be provided with the same information within the same time limit.

If, prior to the expiry of the time limit of 16 months, the applicant requests that documents relating to the application be made available to the public earlier than is prescribed in the Patent Act, he shall provide the information concerning the deposit of the microorganism at the latest at the same time that the request is made. If, prior to the expiry of the time limit of 16 months, a person making an international application requests early publication of the application under Article 21(2)(b) of the Patent Cooperation Treaty, he shall provide the World Intellectual Property Organization with the said information at the latest at the same time that the request is made.

If a deposited culture of a microorganism has been transferred from one international depositary authority to another, in accordance with the Budapest Treaty, the applicant shall, as soon as possible and once he has received a receipt for the transfer of the culture, inform the Patent Office of the transfer and of the new number allotted to the culture.

The Patent Office may require from the applicant a copy of the receipt which the depositary institution has issued regarding the deposit of the culture.

(Regulation, Section 17b.)

3. Duration of Storage

A deposited culture of a microorganism must be continuously on storage.

(Patent Act, Section 8(6).)

4. Conditions for the Furnishing of Samples

A request for furnishing of a sample of a deposited microorganism under the Patent Act must be drawn up in accordance with Rule 11 of the Regulations under the Budapest Treaty.

If a request is made before a final decision has been made on the patent application to which the deposited culture relates, the person requesting the sample must undertake to use the sample solely for research purposes until a final decision has been made on the patent application. The said person must also undertake not to allow any other person access to the sample before a final decision has been taken on the patent application or, if a patent is granted, not before that patent has ceased to have effect.

If the request is made for a sample of a deposited culture of a microorganism which relates to a patent, the person who makes the request must undertake vis-à-vis the proprietor of the patent not to allow to anyone else access to the sample until the patent ceases to have effect.

The person requesting the sample must make the same undertakings in regard to cultures which are derived from the samples and which still exhibit those characteristics important for the use of the invention.

A request must be accompanied by a written declaration that the person requesting the samples undertakes to fulfill the obligations referred to above.

(Regulation, Section 25a.)

A request under the Patent Act to the effect that samples shall be furnished only to experts in the art must be submitted to the Patent Office no later than the date on which the application is made available to the public.

The Patent Office maintains a list of those individuals who, in the opinion of the Patent Office, are experts in the art and who have expressed themselves willing to receive samples. The names of individuals entered on the list are advertised.

If a sample may only be furnished to a specified expert in the art, the request must state the name of the expert who is to undertake the commission. The request must be accompanied by a statement from the expert in which he accepts his obligations vis-à-vis the applicant. In such cases the person who makes the request is not required to make a declaration himself.

Any person entered on the list or any person approved by the applicant in the particular case may be used as an expert.

(Regulation, Section 25b.)

If a request for the furnishing of a sample has been made, and there is nothing to prevent it being granted, the Patent Office issues a certificate to that effect. The Patent Office sends the request and the certificate for furnishing of the sample to the institution where the culture is deposited. At the same time the Patent Office sends the applicant or the patentee copies of the request and the certificate.

If, in the opinion of the Patent Office, the certificate cannot be issued, the Patent Office notifies the person who has requested the sample of this fact. The said person may appeal this decision to the Committee of Appeal within two months from notification by the Patent Office. Rulings on this subject given by the Committee of Appeal cannot be appealed before the courts.

(Regulation, Section 25d.)

IT – ITALY

Italian Patent and Trademark Office
Directorate General for Industrial Production
Ministry of Industry, Commerce and Handicraft
19, via Molise
00187 ROME
Italy

Telephone: (396) 4788 2736
Telex: 620560 UCB I
Telefax: (396) 4705 3035
Internet home page: <http://www.european-patent-office.org.it>

1. Requirements for Deposit

If an invention concerns a microbiological process or the product thereof, involves use of a microorganism which is not available to the public and which cannot be disclosed in such a manner as to enable a person skilled in the art to carry out the invention, a culture of the microorganism must be deposited with a depositary authority for such cultures.

(Royal Decree No. 1127 of 1939, Provisions on Patents for Industrial Inventions, as amended, to 1994, Section 28.)

Furthermore, the application as filed should contain the relevant information available to the applicant on the characteristics of the microorganism.

The application should indicate the authorized depositary authority with which the culture of the microorganism has been deposited, as well as the number and the date of the said deposit. Such information may be submitted within two months from the date of filing the patent application.

(Royal Decree No. 244 of 1940, Regulations on Patents for Industrial Inventions, as amended to 1979, Rule 5*bis*(1).)

2. Time of Deposit

The deposit must be made not later than the date of filing the patent application.

(Regulations, Rule 5*bis*(1).)

3. Duration of Storage

No provision.

4. Conditions for the Furnishing of Samples

(i) Time of Availability of Samples

A sample of a deposited microorganism becomes available as from the date on which the patent application is open to public inspection (normally, 18 months after the filing date).

(Regulations, Rule *5bis*.)

(ii) Restrictions Concerning the Furnishing of Samples

The requesting party should undertake vis-à-vis the applicant or the proprietor of the patent not to make the culture available to any third party and also undertake that the culture will only be used through a named qualified expert for experimental purposes only until the date on which the patent application is rejected or withdrawn or the patent has finally expired or been declared null and void and can no longer be restored in favor of the applicant or the proprietor of the patent. The designated expert is equally responsible for any abuse by the requesting party.

(Regulations, Rule *5bis*.)

JP – JAPAN

Japanese Patent Office (JPO)
Tokkyocho
4-3 Kasumigaseki 3-Chome
Chiyoda-ku
TOKYO 100-8915
Japan

Telephone: (81-3) 3592 13 08

Telefax: (81-3) 3501 06 59

Internet home page: <http://www.jpo-miti.go.jp>

1. Requirements for Deposit

If an invention involves or uses a microorganism which is not available to the public, a culture of the microorganism must be deposited with an official depositary authority designated by the Director General of the Japanese Patent Office or with an international depositary authority under the Budapest Treaty. The National Institute of Bioscience and Human-Technology (NIBH), attached to the Agency of Industrial Science and Technology, Ministry of International Trade and Industry, is designated as an official depositary authority.

(Regulations under the Patent Law No. 121 of 1959, as last amended in 1995, Rule 27*bis*.)

2. Time of Deposit

The applicant must indicate the deposit number in the specification originally attached to the application for a patent registration, and must submit a copy of the most recent receipt of the deposit of the microorganism issued by the depositary authority, when the patent application is filed.

(Regulations, Rule 27*bis*.)

3. Duration of Storage

Under the patent practice of Japan, with regard to national deposits, a deposited microorganism is to be kept in storage until the expiration of the relevant patent, whereas, with regard to international deposits, the duration of storage of microorganisms is at least 30 years.

4. Conditions for the Furnishing of Samples

(i) Time of Availability of Samples

A sample of a deposited microorganism becomes available as from the date of publication of the examined patent application for opposition purposes (Kokoku).

A sample is available, however, even before the date of the said publication, provided that the requesting party is either:

(a) a person who has received a written warning asking him to pay compensation for having commercially worked the invention involving or using the microorganism in question; or

(b) an applicant who has received notice of refusal from the Patent Office, in which case the applicant must reply to such notice.

(Regulations, Rule 27*ter*.)

(ii) Restrictions Concerning the Furnishing of Samples

The furnishing of samples of deposited microorganisms is restricted to the cases where the samples are used for experiments or research purposes. The released sample may not be transferred to third parties.

(Regulations, Rule 27*ter*.)

KR – REPUBLIC OF KOREA

Korean Industrial Property Office (KIPO)
Ministry of Trade, Industry and Energy
Government Complex-Taejon
Dusan-dong, So-ku
TAEJON METROPOLITAN CITY, 302-701
Republic of Korea

Telephone: (8242) 481 5064 – 5072
Telefax: (8242) 472 3459
E-mail: kipoicd@kipo.go.kr
Internet home page: <http://www.kipo.go.kr>

1. Requirements for Deposit

If an invention involves a microorganism which cannot be obtained easily by any person skilled in the art, the patent applicant must deposit a culture of the microorganism with a depositary institution having acquired the status of international depositary authority or with a depositary institution designated by the Commissioner of the Korea Industrial Property Office.

(Presidential Decree No. 12199 of 1987, Article 2(1).)

2. Time of Deposit

The name of the depositary institution with which the microorganism has been deposited, the number of the deposit and the date of deposit must be specified in the patent application and the receipt of the deposit must be filed with the Commissioner of the Korea Industrial Property Office.

(Presidential Decree, Article 2(2).)

3. Duration of Storage

No provision.

4. Conditions for the Furnishing of Samples

(i) Time of Availability of Samples

Samples of deposited microorganisms are available to any requesting party after the publication of the patent application.

(Presidential Decree, Article 2-2(1).)

(ii) Restrictions Concerning the Furnishing of Samples

The requesting party must undertake that samples of the deposited microorganism shall be used for experimental and research purposes in the Republic of Korea and shall not be made available to any third party.

(Presidential Decree, Article 2-2(1).)

LI – LIECHTENSTEIN

Office of National Economy
Intellectual Property
9490 VADUZ
Liechtenstein

Telephone: (075) 236 61 11
Telex: 889 290 REPI FL
Telefax: (075) 236 68 89

Swiss law applies.

LT – LITHUANIA

State Patent Bureau
Algirdo g. 31
2600 Vilnius

Telephone: (3702) 23 33 49
Telefax: (3702) 26 34 69
E-mail: saule.daukuviene@is.lt
Internet home page: <http://www.is.lt/vpb/engl>

1. Requirements for Deposit

No provision.

2. Time of Deposit

No provision.

3. Duration of Storage

No provision.

4. Conditions for the Furnishing of Samples

No provision.

LV – LATVIA

Patent Office of the Republic of Latvia
a/k 124
1010 RIGA
Latvia

or: Citadeles iela 7 (70)
1010 RIGA

or: P.O. Box 824
1010 RIGA

Telephone: (371-7) 027 577
Telefax: (371-7) 027 208

1. Requirements for Deposit

If an invention relates to the use of a specific microorganism with restricted availability, the applicant must submit a document to the Patent Office on the deposit of the culture of the respective microorganism in one of the international depositary authorities.

(Patent Law, 1995, Article 7(8).)

2. Time of Deposit

The document on the deposit of the culture of the respective microorganism should be filed with the Patent Office either along with the application or no later than three months from the filing date of the application.

3. Duration of Storage

No provision.

4. Conditions for the Furnishing of Samples

No provision.

MC – MONACO

Intellectual Property Division
Department of Economic Expansion
Ministry of Finance and Economy
B.P. 665
MC-98014 MONACO Cédex

or: 9, rue du Gabian
MC-98000 Monaco

Telephone: (377) 93 15 8000

Telefax: (377) 92 05 75 20

Internet home page: <http://www.european-patent-office-org/patlib/country/monaco/>

1. Requirements for Deposit

No provision.

2. Time of Deposit

No provision.

3. Duration of Storage

No provision.

4. Conditions for the Furnishing of Samples

No provision.

MD – REPUBLIC OF MOLDOVA

State Agency on Industrial Property Protection (AGEPI)
24/1 Andrei Doga Street
2024 KISHINEV
Republic of Moldova

Telephone: (3732) 44 32 53; 44 31 39
Telefax: (3732) 44 01 19; 44 32 53
E-mail: office@agepi.md
Internet home page: <http://www.agepi.md>

1. Requirements for Deposit

An application for a patent involving a microorganism must include a document proving the deposit of the microorganism and containing the information about the deposit number of the culture of the microorganism, the place of the culture collection with which it is deposited, the date of deposit, the name of the culture of the microorganism and its morphology, taxonomy and biochemical characteristics.

(The Instructions for Drafting and Filing Applications for Granting of Patents of Inventions, Chapter 30, Items 30.1 and 30.2.)

2. Time of Deposit

The deposit of the microorganism must be made not later than the date of filing of the patent application.

(The Instructions for Drafting and Filing Applications for Granting of Patents for Inventions, Chapter 30, Item 30.3.)

3. Duration of Storage

No provision.

4. Conditions for the Furnishing of Samples

No provision.

NL – NETHERLANDS

Netherlands Industrial Property Office
Ministry of Economic Affairs
P.O. Box 5820
2280 HV RIJSWIJK
Netherlands

or: Patentlaan 2
2288 EE RIJSWIJK

Telephone: (31-70) 398 6655
Telex: 33265 OCTRD NL
Telefax: (31-70) 390 0190

1. Requirements for Deposit

Where an invention involves the use of a microorganism,

(1) The specification of the invention shall:

(a) contain the data at the disposal of the applicant which are relevant to the properties of the microorganism;

(b) mention the institution with which, the number under which and the date on which the culture of the microorganism has been deposited.

(2) Together with the application shall be submitted:

(a) a declaration to the effect that the applicant, pursuant to Section 31F, irrevocably gives permission for the furnishing of samples of the culture of the microorganism deposited by him;

(b) a copy of the receipt issued by the institution with which the culture of the microorganism has been deposited;

(c) a copy of the declaration referred to in Section 31D.

(3) The number referred to in paragraph (1)(b) and the copy referred to in paragraph (2)(b) may also be furnished within a time limit of one month after the filing of the application.

(Patents Rules, as amended to 1991, Section 31B.)

A deposit of a microorganism shall be accompanied by a written statement of the depositor, containing:

- (a) a declaration stating the circumstances as well as the properties of the microorganism which are of interest for the cultivation, the storage, the handling and the viability of the microorganism;
- (b) an indication of the method permitting the checking of the presence of the microorganism;
- (c) an identification reference and, where possible, the scientific description and the proposed taxonomic designation of the microorganism.

(Patents Rules, as amended to 1991, Section 31D.)

- (4) The deposit of cultures of microorganisms may be effected with:

- (a) an institution which, pursuant to Article 7 of the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure has acquired the status of international depositary authority, or
- (b) an institution designated by the Patent Office.

(Patents Rules, as amended to 1991, Section 31C(1).)

2. Time of Deposit

The deposit of a microorganism must be made at the date of filing of the patent application.

(Patents Rules, as amended to 1991, Section 31B.)

3. Duration of Storage

The depositary institution shall store the deposited microorganisms at least for 30 years after the date of deposit.

(Patents Rules, as amended to 1991, Section 31C(c).)

4. Conditions for the Furnishing of Samples

(i) Time of Availability of Samples

(1) The culture of a deposited microorganism shall be available from the date of filing of the relevant patent application for the furnishing of samples in pursuance of Section 31F until the date on which it has become certain no patent will be granted on this application or until the date on which the patent granted on that application has lost its effect.

(2) Where the culture of a microorganism ceases to be available with the institution with which the culture has been stored because the microorganism is not viable any more or the institution is not capable of furnishing samples of that culture for other reasons and the culture has not been transferred to another institution as referred to in Section 31C(1) where it remains accessible, it shall nevertheless be considered to have remained available where within a time limit of three months after the date on which the institution or the Patent Office has notified the depositor of the fact that the culture is no longer available, a new deposit of the relative microorganism is effected and a copy of the receipt of the new deposit, issued by the relevant institution, indicating the number of the patent application or the patent, has been sent to the Patent Office.

(3) Paragraph (2) shall apply mutatis mutandis where the institution with which the culture has been stored has discontinued the performance of its functions in respect of the cultures of microorganisms deposited with it or where it does not comply any more with the specification in Section 31C(1), provided that the time limit of three months referred to in paragraph (2) shall begin on the date on which that fact has been notified in the Journal referred to in Section 38.

(4) Any new deposit as referred to in paragraph (2) shall be accompanied by a statement signed by the depositor that the culture of the microorganism deposited anew is identical to the original deposit.

(5) Where a fact as referred to in paragraph (3) presents itself, the Patent Office shall as soon as possible make notification of it in the Journal referred to in Section 38.

(Patents Rules, as amended to 1991, Section 31E.)

(ii) Restrictions Concerning the Furnishing of Samples

(1) Any person who is entitled in pursuance of Section 28A of the Patents Act of the Kingdom to inspection of the documents referred to in that Section in respect of a patent application or a patent may make a request for the furnishing of a sample of the culture of a microorganism, deposited pursuant to Section 22B(2) of the Patents Act of the Kingdom, to which that application or that patent is related.

(2) The request shall be addressed to the Patent Office by means of a form prescribed by the Patent Office. It shall be accompanied by a statement written by the person who makes the request declaring that he commits himself in respect of the deposited culture or a culture

derived from it vis-à-vis the person who filed the patent application or the proprietor of the patent until the date on which it has become certain no patent will be granted on that patent application or, where a patent has been granted, for the period it remains in force:

(a) not to make it available to third parties;

(b) to use it exclusively for tests, unless the person who made the request uses the culture as the proprietor of a license ensuing from the provisions of Section 34 or Section 34B of the Patents Act of the Kingdom or as a person entitled to do so pursuant to Section 34A of the Patents Act of the Kingdom.

(3) The applicant for a patent may until the date on which the application is laid open to public inspection pursuant to Section 22C of the Patents Act of the Kingdom or, where this takes place on an earlier date, until the date of publication of the application pursuant to Section 25 of that Act of the Kingdom, notify the Patent Office on a form prescribed for the purpose by the Patent Office that until the date on which the patent is granted or until the date on which it is certain that no patent will be granted on the application, furnishing of samples of the culture of a microorganism deposited by him in pursuance of paragraph (1) may only be performed to an expert designated by the person who made the request. The statement referred to in paragraph (2), second sentence shall be co-signed in that case by the relative expert.

(4) As an expert may be designated:

(a) any natural person relative to whom the person who makes the request proves on filing the request that the applicant for the patent has approved of his designation;

(b) any natural person acknowledged as an expert by the President of the Patent Office.

(5) By a derived culture shall be meant for the application of paragraph (2) any culture preserving the properties of the deposited culture essential for the carrying out of the invention. The commitments referred to in paragraph (2) shall not form an impediment for the deposit of a derived culture necessary for the procedure for the grant of a patent.

(6) The Patent Office shall send the request to the institution. At the same time the Patent Office shall mention whether a patent application containing notification of the deposit of the microorganism has been filed and whether the person who made the request is entitled to being furnished with a sample of that microorganism. The Patent Office shall send a copy of the request to the applicant for a patent or the proprietor of the patent.

(Patents Rules, as amended to 1991, Section 31F.)

NO – NORWAY

Norwegian Patent Office
Postboks 8160 Dep.
0033 OSLO
Norway

or: K benhavnsgaten 10
0033 OSLO

Telephone: (47) 22 38 73 00
Telex: 19152 NOPAT N
Telefax: (47) 22 38 73 01

1. Requirements for Deposit

If the invention relates to a microbiological process or to a product obtained by such process, and if the carrying out of the invention involves the use of a microorganism which is not available to the public, a culture of that microorganism shall be deposited in order to disclose the invention in a sufficiently clear manner.

(Patents Act of 1967, as amended to 1985, Section 8(a).)

2. Time of Deposit

The deposit must be made on the day of filing of the patent application at the latest.¹

(Patents Act, Section 8(a).)

3. Duration of Storage

The deposit shall be made in accordance with the Budapest Treaty (i.e., for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism was received by the authority and, in any case, for a period of at least 30 years after the date of the deposit).

(Patent Regulations, Section 17(a).)

¹ The question of the time of deposit where the priority of a foreign application is claimed is left open in the Patents Act.

4. Conditions for the Furnishing of Samples

(i) Time of Availability of Samples

A sample of a deposited microorganism becomes available when the documents of the application have been made available to the public.

(Patents Act, Section 22.)

(ii) Restrictions Concerning the Furnishing of Samples

Samples must not be furnished to anyone who, in accordance with the law or other ordinance, may not handle the deposited microorganism, nor may they be furnished to anyone whose handling of the samples may be assumed to involve evident risk in view of the harmful properties of the microorganism.

(Patents Act, Section 22, paragraph 7.)

The patentee may request that a sample of the deposited microorganism be available only to an expert in the art until the patent application has been laid open to public inspection or has been finally decided upon without having been laid open to public inspection. An expert is a person whose name is included in a list published in the Patent Office for the purpose of handling samples of deposited microorganisms.

The request for the furnishing of a sample must be filed in writing with the Patent Office and must contain a declaration of compliance with the following restrictions on the use of the sample:

(a) If the request is made before the patent application referring to the deposit of a microorganism has been finally decided upon, the requesting party must undertake vis-à-vis the applicant to use the sample of the microorganism deposited for experimental purposes only, until the patent application is finally decided upon, and not to make the sample available to any third party within the same period or, if a patent is granted, before the expiry of the patent.

(b) If the request is made after a patent referring to the deposit of a microorganism is granted, the requesting party shall undertake vis-à-vis the owner of the patent not to make the sample of the deposited microorganism available to any third party before the expiry of the patent.

If a sample of the deposited microorganism may only be issued to a special expert, the expert shall make the declaration referred to above.

(Patents Act, Section 22, paragraphs 8 and 9; Patent Regulations, Sections 25(a) and 25(b).)

PH – PHILIPPINES

Bureau of Patents, Trademarks and Technology Transfer
Department of Trade and Industry
P.O. Box 296
MANILA
Philippines

Telephone: (63-2) 890 48 62
Telex: 14830 MTI PS
Telefax: (63-2) 890 4936
E-mail: ipo@dti.gov.ph
Internet home page: <http://www.dti.gov.ph/ipo>

1. Requirements for Deposit

The deposit with a public depositary institution of recognized standing of a microorganism which is the subject of a patent application is obligatory in order to describe the invention adequately.

2. Time of Deposit

If at the time of filing a patent application no deposit of a culture of the microorganism has been made in a recognized public depositary institution but a taxonomic description of the microorganism, its source and method of isolation have been set forth in the patent application as filed, the Office requires deposit to be made and requires submission of proof of such deposit together with the deposit number or identification number assigned to it by the depositary institution.

If at the time of filing of a patent application the applicant(s) has (have) deposited in a recognized depositary institution before or at the time of filing of the patent application the culture of the strain of microorganism, the application may be amended to include the taxonomic description of the microorganism, provided a sworn statement is filed to the effect that the taxonomic description sought to be entered in the application corresponds to the microorganism as deposited and properly identified, and provided further that evidence of deposit of the microorganism and its identification number as assigned to it by the depositary institution is submitted to the Office.

3. Duration of Storage

The depositary institution should be under contractual obligation to place the culture in permanent collection.

4. Conditions for the Furnishing of Samples

The depositary institution must provide access to the culture to persons who have interest therein in regard to matters relating to the patent as soon as it is issued.

PL – POLAND

Patent Office of the Republic of Poland
P.O. Box 203
00-950 WARSAW
Poland

or: Aleja Niepodleglosci 188-192
00-950 WARSAW
Poland

Telephone: (4822) 825 80 01
Telex: 813492 CPIZI PL
Telefax: (4822) 825 05 81
E-mail: urzadpat@plearn.edu.pl
Internet home page: <http://saturn.ci.uw.edu.pl/up/>

1. Requirements for Deposit

The Institute of Biotechnology of the Agriculture and Food Industry is appointed by the Patent Office to perform the functions of a national depositary institution. The requirements of deposit of microorganisms with the said Institute are in conformity with the Budapest Treaty.

2. Time of Deposit

Under the existing practice, the deposit must be made at the filing date of the patent application.

3. Duration of Storage

Under the existing practice, the duration of storage is that of the life of the patent, plus three additional years.

4. Conditions for the Furnishing of Samples

Under the existing practice, samples of deposited microorganisms are furnished to the Patent Office, upon request, and to any other requesting party, on condition that the request is communicated to the depositor and that the requesting party declares that he will use the sample only for experimental purposes and that he will not make it available to any third party.

PT – PORTUGAL

National Institute of Industrial Property
Campo das Cebolas
1100 LISBON
Portugal

Telephone: (351-1) 888 1101
Telex: 18356 INPI P
Telefax: (351-1) 887 5308
Internet home page: <http://www.inpi.pt>

1. Requirements for Deposit

If the patent application mentions a biologically reproducible material which may not be described in such a way as to enable those skilled in the art to carry out the invention, and if the material is not available to the public, the application must be completed by depositing the material with an authorized depositary institution.

All the available characteristics of the microorganism required for it to be correctly identified must be indicated, including the name and address of the depositary institution and the date and number of the deposit of the culture.

The characteristics of the microorganism must be submitted to the National Institute of Industrial Property within 16 months after the date of filing of the application in Portugal or, if a priority is claimed, after the priority date.

(Industrial Property Code, Decree Law No. 16/95 of 1995, Article 59(1), (3) and (4)).

2. Time of Deposit

The microorganism must be deposited no later than the date of the patent application in Portugal or, if a priority is claimed, no later than the date of priority.

(Industrial Property Code, Article 59(2)).

3. Duration of Storage

No provision.

4. Conditions for the Furnishing of Samples

Access to the deposited culture of microorganism may only be given at the depositary institution, as from the date of publication of the patent application.
(Industrial Property Code, Article 59(5)).

RO – ROMANIA

State Office for Inventions and Trademarks
Postal Office (P.O.) 1 - Box 52
70418 Bucarest

5, Ion Ghica Street, Sect. 3
70018 Bucarest

Telephone: (401) 315 90 66; 313 24 92
Telefax: (401) 312 38 19
E-mail address: office@osim.ro
Internet home page: <http://www.osim.ro>

1. Requirements for Deposit

No provision.

2. Time of Deposit

No provision.

3. Duration of Storage

No provision.

4. Conditions for the Furnishing of Samples

No provision.

RU – RUSSIAN FEDERATION

Russian Agency for Patents and Trademarks
30-1, Berezhkovskaya nab.
121858 MOSCOW
Russian Federation

Telephone: (7-095) 240 5822
(7-095) 240 5888 (PCT Applications)
Telefax: (7-095) 243 3337
E-mail: vniigpe@online.ru
Internet home page: <http://www.rupto.ru>

1. Requirements for Deposit

Information concerning the possibility of the carrying out of an invention involving a strain of a microorganism, culture of plant or animal cells may be confirmed by submitting the description of the method for producing thereof or a document certifying the deposition of a microorganism in the prescribed manner.

(Rule for Compiling, Filing and Examining an Application for the Grant of a Patent for Invention, Rule 3.2.4.5(4))

When the subject matter of a patent application for an invention involves a strain of a deposited microorganisms, culture of plant or animal cells, the claims must include a reference to the abbreviation of the official name of the depositary institution with which the strain of a microorganism or the culture has been deposited, and the deposit number given to the deposit.

(Regulations for Drawing up and Filing Applications for the Grant of Patents for Inventions, 1993, Rule 11.3.5)

2. Time of Deposit

The deposit of the microorganisms must be made not later than the priority date of the patent application.¹

(Rules for Compiling, Filing and Examining an Application for the Grant of a Patent for Invention, Rule 3.2.4.5(4))

¹ The question of the time of deposit where the priority of a previous application is claimed is under consideration.

3. Duration of Storage

For depositing with an international depositary authority under the Budapest Treaty, the provisions of the Rule 9 of the Regulations under the said Treaty are applied.

4. Conditions for the Furnishing of Samples

Provisions concerning conditions for furnishing of samples are under preparation.

SE – SWEDEN

Swedish Patent and Registration Office (SPRO)
P.O. Box 5055
10242 STOCKHOLM
Sweden

Telephone: (468) 782 25 00
Telex: 179 78 PATOREG-S
Telefax: (468) 270 173 51
Internet home page: <http://www.prv.se/prveng/front.htm>

1. Requirements for Deposit

A culture of a microorganism must be deposited if the carrying out of the invention involves the use of a microorganism which is neither available to the public nor describable in the patent application in such a manner as to enable a person skilled in the art to carry out the invention.

(Patents Act of 1967, as amended to 1983, Section 8(a).)

2. Time of Deposit

The deposit of a microorganism must be made not later than the date of filing of the patent application.

(Patents Act, Section 8(a).)

3. Duration of Storage

The deposit shall be made in accordance with the Budapest Treaty (i.e., for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism was received by the authority and, in any case, for a period of at least 30 years after the date of the deposit).

(Decree on Patent Formalities of 1967, as amended to 1983, Section 17(a).)

4. Conditions for the Furnishing of Samples

(i) Time of Availability of Samples

A sample of a microorganism becomes available as from the date on which the patent application is made available to the public.

If a culture of a microorganism has been deposited according to Section 8a, any person has the right to obtain a sample from the culture after the documents have become available to anyone in accordance with the following rules.

When 18 months have passed from the day when the patent application was filed or, if priority is claimed, from the day from which priority is claimed, the documents shall be available to anyone, even if the application has not been laid open to public inspection. However, if a decision has been made to dismiss or reject an application, the documents shall be made available only if the applicant requests that the application be resumed, lodges appeal, or makes a petition pursuant to Section 72 or 73 of the Patents Act.

At the applicant's request, the documents shall be made available earlier than set out in the first and second paragraphs.

When the documents become available pursuant to either of the two aforementioned circumstances, this fact shall be announced.

If a document contains business secrets and if it does not concern the invention for which a patent is sought, the Patent Authority, upon request and if there are special reasons for this, may order that the document shall not be made available. If such a request has been made, the document shall not be made available until the request has been refused by a decision which has taken legal effect.

(Patents Act, Section 22.)

(ii) Restrictions Concerning the Furnishing of Samples

The patentee may request that a sample of the deposited microorganism be available only to an expert in the art until the patent application has been laid open to public inspection or has been finally decided upon without having been laid open to public inspection. An expert is a person whose name is included in a list published in the Patent Office for the purpose of handling samples of deposited microorganisms.

This does not mean, however, that samples are issued to anyone who in consequence of provisions in a law or other ordinance may not handle the deposited microorganism. Nor does this mean that samples are issued to anyone whose handling of the sample can be assumed to involve an evident risk in view of the harmful properties of the organism.

(Patents Act, Section 22; Patents Decree, Section 25(b).)

The request for the furnishing of a sample must be filed in writing with the Patent Office and must contain a declaration of compliance with the following restrictions on the use of the sample:

(a) If the request is made before the patent application referring to the deposit of a microorganism has been finally decided upon, the requesting party must undertake vis-à-vis the applicant to use the sample of the microorganism deposited for experimental purposes only, until the patent application is finally decided upon, and not to make the sample available to any third party within the same period or, if a patent is granted, before the expiry of the patent.

(b) If the request is made after a patent referring to the deposit of a microorganism is granted, the requesting party shall undertake vis-à-vis the owner of the patent not to make the sample of the deposited microorganism available to any third party before the expiry of the patent.

(Patents Decree, Section 25(a).)

If a sample of the deposited microorganism may only be issued to a special expert, the expert shall make the declaration referred to above.

(Patents Decree, Section 25(b).)

SG – SINGAPORE

Registry of Trade Marks and Patents
51 Bras Basah Road
#04.01 Plaza By The Park
SINGAPORE 189554

Telephone: (65) 330 2700; 2720
Telefax: (65) 339 0252
Internet home page: <http://www.gov.sg/molaw/rtmp/>

1. Requirements for Deposit

The deposit of a microorganism shall be made if an invention requires for its performance the use of a microorganism which is not available to the public at the date of filing of the patent application and which cannot be described in such a manner as to enable the invention to be performed by a person skilled in the art. The name of the international depositary authority, the date when the culture was deposited and the accession number of the deposit should be given in the specification of the application, and a copy of the receipt issued by the international depositary authority in accordance with Rule 7 of the Regulations under the Budapest Treaty should also be filed.

(a) within 16 months from

- (i) the declared priority date; or
- (ii) the date of filing the application where there is no declared priority date;

(b) where, on a request made by the applicant, the Registrar publishes the application before the end of the period prescribed for the purposes of section 27(1), before the date of the request; or

(c) where the Registrar sends notification to the applicant that, in accordance with Section 108(4), he has received a request by any person for information and inspection of documents under subsection (1) of that Section, before the end of one month after his sending to the applicant notification of his receipt of the request.

(The Patents Rules 1995, Rule 20, Schedule 4, paragraph 1.)

2. Time of Deposit

The deposit must be made not later than the date of filing the patent application.

(The Patents Rules 1995, Rule 20, Schedule 4, paragraph 1(2)(a)(i).)

3. Duration of Storage

No provision.

4. Conditions for the Furnishing of Samples

(i) Time of Availability of Samples

A culture of a deposited microorganism is available upon request before publication of the relevant patent application to a person to whom Section 108(4) applies and who has made a request under Section 108(1) and is available upon such publication to any person.

(The Patent Rules 1995, Rule 20, Schedule 4, paragraph 2(1).)

(ii) Restrictions for the Furnishing of Samples

A request authorizing the furnishing of samples shall comprise on the part of the person to whom the request relates, undertakings for the benefit of the applicant for, or proprietor of, the patent:

(a) not to make the culture, or any culture derived from it, available to any other person; and

(b) not to use the culture, or any culture derived from it, otherwise than for experimental purposes relating to the subject matter of the invention.

Both undertakings shall have effect until the patent application has been withdrawn, has been taken to be withdrawn, has been treated as having been abandoned, has been refused or is treated as having been refused (including any further period allowed under Rule 105 or Rule 113(1) or (4) but excluding, where an application is reinstated under either of those rules, the period before it is reinstated).

Where the patent is granted, the undertaking in subparagraph (a), above, shall also have effect during the validity of the patent and during the period of six months referred to in Section 36(3).

The undertaking set out in subparagraph (b), above, shall not have effect after the date of publication in the Official Journal (Patents) of a notice that the patent has been granted.

The request for the furnishing of samples should be made on Patents Form 53.

(The Patents Rules 1995, Rule 20, Schedule 4, paragraph 2(3).)

Before the preparations for publication of a patent application under Section 27 have been completed, the applicant may give notice to the Registrar on Patents Form 54 of his

intention that a sample of the microorganism should be furnished only to an expert. Where this has been done, the Registrar will publish with the application a notice to this effect and persons requesting samples must nominate an expert who must have given undertakings in accordance with subparagraphs (a) and (b), above. The request for the furnishing of samples in these circumstances should be made on Patents Form 55. The Registrar shall specify the period within which the patent applicant may object to the furnishing of a sample of the microorganism to the particular expert nominated.

In the case of an international application, the applicant's notice that a sample should be furnished only to an expert should be given in writing to the International Bureau under Rule 13bis.3 of the Regulations under the Patent Cooperation Treaty before technical preparations for international publication are complete.

(The Patent Rules 1995, Rule 20, Schedule 4, paragraph 3(1) and (4).)

SI – SLOVENIA

Slovenian Intellectual Property Office (SIPO)
Kotnikova 6
1000 LJUBLJANA
Slovenia

Telephone: (386-61) 178 3000
Telefax: (386-61) 178 3111
Internet home page: <http://www.sipo.mzt.si/>

1. Requirements for Deposit

No provision.

2. Time of Deposit

No provision.

3. Duration of Storage

No provision.

4. Conditions for the Furnishing of Samples

No provision.

SK – SLOVAKIA

Industrial Property Office
of the Slovak Republic
Svermova 43
97401 BANSKÁ BYSTRICA
Slovakia

Telephone: (421-88) 41 32 530
Telefax: (421-88) 41 32 566
Internet home page: www.indprop.gov.sk

1. Requirements for Deposit

The deposit of a culture of a microorganism with a public depositary institution in Slovakia or abroad is required if the invention involves a microorganism involved in industrial production. The number of the deposit given to the microorganism by the depositary institution must be specified in the patent application.

(Law on Inventions, Industrial Designs and Rationalization Proposals No. 527 of November 27, 1990, Section 26(2).)

In accordance with the practice followed, the applicant must attach to the patent application proof that the microorganism has been deposited.

2. Time of Deposit

In accordance with the practice followed, the deposit of the microorganism must be made not later than the date of filing of the patent application.

3. Duration of Storage

No provision.

4. Conditions for the Furnishing of Samples

No provision.

TJ – TAJIKISTAN

National Center for Patents and Information
14a, Ainy Street
734042 DUSHANBE
Tajikistan

Telephone: (7377-2) 275 977; 275 987
Telefax: (7377-2) 217 154

1. Requirements for Deposit

No provision.

2. Time of Deposit

No provision.

3. Duration of Storage

No provision.

4. Conditions for the Furnishing of Samples

No provision.

TT – TRINIDAD AND TOBAGO

Intellectual Property Registry
Companies Section
Registrar General's Department
34 Frederick Street
PORT OF SPAIN
Trinidad and Tobago

Telephone: (1-868) 627 9567
Telefax: (1-868) 624 1221
E-mail: Correspondence.IPOffice@opus.co.tt

1. Requirements for Deposit

No provision.

2. Time of Deposit

No provision.

3. Duration of Storage

No provision.

4. Conditions for the Furnishing of Samples

No provision.

TR – TURKEY

Turkish Patent Institute
Izmir Cad. No. 26
06440 KIZILAY – ANKARA
Turkey

Telephone: (90 312) 232 5415/6
Telefax: (90 312) 232 5437
Internet home page: <http://www.turkpatent.gov.tr>

1. Requirements for Deposit

No provision.

2. Time of Deposit

No provision.

3. Duration of Storage

No provision.

4. Conditions for the Furnishing of Samples

No provision.

UA – UKRAINE

State Patent Office of Ukraine
8 Lvivska Ploscha
254655 KYIV 53, DSP-655
Ukraine

Telephone: (38044) 212 50 82
Telefax: (38044) 212 34 49; 295 63 00

Provisions on the procedure for the deposit of microorganisms in connection with patent applications are contained in the Regulations on the Filing of Applications for Patents and Utility Models in Ukraine, No. 318/528 of December 27, 1994, and in the Instructions on Deposit in Ukraine of Strains of Microorganisms for the Purposes of Patent Procedure, No. 286/822, of August 4, 1995.

Information on the above provisions may be obtained from the State Patent Office of Ukraine (see above).

US – UNITED STATES OF AMERICA

Patent and Trademark Office (USPTO)
Box 4
U.S. Department of Commerce
WASHINGTON, D.C. 20231
United States of America

Telephone: (1-703) 305 8600
Telex: 710-955-0671
Telefax: (1-703) 305 8885
Internet home page: <http://www.uspto.gov/>

1. Requirements for Deposit

The applicant must deposit a culture of the microorganism with a depositary authority, if the invention depends on the use of microorganisms which are unavailable to the public. The depositor may make the required deposit in an international depositary authority recognized under the Budapest Treaty or in a depositary institution meeting the same requirements.

(Patent and Trademark Office, Manual of Patent Examining Procedure, 1983, Section 608.01(p), as revised in 1992.)

2. Time of Deposit

The deposit of the microorganism must be made by the time the patent issue fee is paid.

(Manual, Section 608.01(p).)

3. Duration of Storage

A deposit must be made for a term of at least 30 years after the date of deposit and at least five years after the most recent request for furnishing a sample of the deposit. For deposits not made under the Budapest Treaty, the term of deposit shall in no case expire prior to the term of the patent.

4. Conditions for the Furnishing of Samples

(i) Time of Availability of Samples

The deposited microorganism must be available to the public at the date of the grant of the patent.

(Manual, Section 608.01(p).)

(ii) Restrictions Concerning the Furnishing of Samples

Any restriction of public access to samples of deposited microorganisms must be removed from the date of grant of the relevant patent.

(Manual, Section 608.01(p).)

YU – YUGOSLAVIA

Federal Intellectual Property Office
Federal Ministry for Development, Science
and Environment
Bulevar Avnoja 104
11070 BELGRADE
Yugoslavia

Telephone: (381-11) 311 11 62
Telefax: (381-11) 311 23 77
E-mail: yupat@gov.yu

1. Requirements for Deposit

If a microorganism is the subject of a microbiological invention, which is not available to the public and which cannot be described in the patent application in such a manner as to enable the invention to be performed by a person skilled in the art with no additional effort, the invention will be considered as described in a sufficiently clear and complete manner in accordance with Article 78(2) of the Law on the Protection of Inventions, Technical Improvements and Distinctive Signs, only if the following conditions have been fulfilled:

- the sample of the microorganism has been deposited in a recognized depositary institution under Article 24 of the Rules of Procedure, at the latest on the day of filing of the patent application;
- the patent application contains all data on the microorganism known to the applicant;
- the patent application contains the name and address of the depositary institution, the official number and date of deposit.

(Rules of Patent Grant Procedure, Article 21(1).)

2. Time of Deposit

The deposit of the microorganism must be made not later than the date of filing of the patent application.

(Rules of Patent Grant Procedure, Article 21(1)(i).)

3. Duration of Storage

No provision.

4. Conditions for the Furnishing of Samples

(i) Time of Availability of Samples

A sample of a deposited microorganism becomes available to everyone as from the date of publication of the patent application.

(Rules of Patent Grant Procedure, Article 22(1).)

(ii) Restrictions Concerning the Furnishing of Samples

From the date of publication of the patent application, a sample of the deposited microorganism is available to everyone, on request. The availability of the microorganism on request depends on the following conditions:

(a) the request must be filed with the Patent Office, in two copies, on the form prescribed by the Office;

(b) the Office confirms, on the request form, that the patent application has been filed, on which the requesting party states the existence of the deposit of the microorganism and his right to ask that a sample of the microorganism should be made available to him;

(c) the requesting party is obliged not to make the requested sample of the microorganism available to third persons until the conclusion of the examination procedure concerning the patent application;

(d) the requesting party makes the undertaking to the patent applicant that the requested sample of the deposited microorganism shall be used exclusively for experimental or research purposes until the publication of the decision to grant the patent.

The obligation under point (d) above does not apply if the requesting party uses the furnished sample of the deposited microorganism on the basis of a compulsory or ex officio license.

(Rules of Patent Grant Procedure, Article 22(2) and (3).)

ZA – SOUTH AFRICA

Office of the Registrar of Patents, Trade Marks, Designs and Copyright
Department of Trade and Industry
Bag X400
PRETORIA 0001
South Africa

Telephone: (27-12) 310 87 01
Telefax: (27-12) 323 42 57
Telex: (9) 35-0168 TRIN

1. Requirements for Deposit

If the complete specification accompanying a patent application claims as an invention a microbiological process or a product thereof, and requires for the performance of the invention the use of a microorganism which is not available to the public on the date of lodging the application and which cannot be made or obtained on the basis of the written description in the specification, a culture of the microorganism must be deposited with a depositary institution which has acquired the status of international depositary authority under the Budapest Treaty.

The complete specification must state the name of the international depositary authority with which the culture was deposited, the date of deposit and the accession number given to the deposit by the international depositary authority. This information may be added to the patent specification at any time before the date of publication or before the opening to public inspection of the patent application, whichever is the earlier.

The complete specification, as lodged, must give such relevant information as is available to the applicant on the characteristics of the microorganism.

(Patents Act No. 57 of 1978, Section 32(6); Patent Regulations 1978, as amended to 1997, Rule 28A(1) and (2)).

2. Time of Deposit

A culture of a microorganism must be deposited not later than the date of filing of the patent application.

(Patent Regulations, Rule 28A(1)(a)).

3. Duration of Storage

No provision.

4. Conditions for the Furnishing of Samples

(i) Time of Availability of Samples

The communication in the patent specification of the information concerning the microorganism is considered as constituting the unreserved and irrevocable consent of the applicant to make the deposited culture available to the public from the date of publication or after the opening to public inspection of the patent application, whichever is earlier.

(Patent Regulations, Rule 28A(3)).

(ii) Restrictions Concerning the Furnishing of Samples

A sample of the deposited culture is furnished to any requesting party from the date of publication or after the opening to public inspection of the patent application, provided that the requesting party makes a valid request therefor to the international depositary authority with which the culture is deposited.

A request for the furnishing of a sample of the deposited culture is valid if it is made on Patents Form P23 on which the Registrar has certified that a patent or patent application referring to the deposit of the culture has been published or has come open to public inspection and that the requesting party is entitled to the furnishing of a sample of the deposited culture.

The Registrar does not make the certification unless the Registrar has received an application on a Patents Form P24 requesting the certification. The application must contain an undertaking from the requesting party *vis à vis* the patentee that the requesting party will not make the deposited culture, or any culture derived therefrom, available to any third party until the patent ceases to have effect by way of expiration, revocation, voluntary surrender, or lapsing without the possibility of renewal in accordance with Section 46 of the Patents Act.

The undertaking *vis à vis* the patentee does not prevent the requesting party from depositing with an international depositary authority a derived culture or the culture itself necessary for the purpose of complying with section 32(6) of the Patents Act.

A derived culture is deemed to be any culture of the microorganism which exhibits those characteristics of the deposited culture which are essential to the carrying out of the invention described in the complete specification in which reference is made to the deposited culture.

(Patent Regulations, Rule 28A(4)(5)(6)(7) and (8)).

AP – AFRICAN REGIONAL INDUSTRIAL PROPERTY ORGANIZATION (ARIPO)

P.O. Box 4228
HARARE
Zimbabwe

Or: Corner Samora Machel Avenue
112 Fourth Street
Harare
Zimbabwe

Telephone: (263-4) 79 43 38
Telefax: (263-4) 70 40 25
E-mail: aripo@harare.iafrica.com

1. Requirements for Deposit

No provision.

2. Time of Deposit

No provision.

3. Duration of Storage

No provision.

4. Conditions for the Furnishing of Samples

No provision.

EA – EURASIAN PATENT ORGANIZATION (EAPO)

M. Cherkassky per. 2/6
Moscow, Centre, GSP, 10362
Russian Federation

Telephone: (7095) 206 62 37; 928 56 12
Telefax: (7095) 921 24 23
E-mail: eapv@euraspo.msk.ru

1. Requirements for Deposit

(1) The Eurasian application shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art.

(2) Where the Eurasian application relates to a microorganism strain or a process involving the use of such a strain that cannot be disclosed in the application in a manner sufficiently clear and complete for invention to be carried out by a person skilled in the art and there is no free access to such microorganism strain with a competent depositary authority in accordance with the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure of April 28, 1977, or with any other depositary institution recognized by the Administrative Council. The deposit shall be effected no later than on the filing date of the Eurasian application.

(Rule 11 of the Patent Regulations under the Eurasian Patent Convention.)

2. Time of Deposit

No provision.

3. Duration of Storage

No provision.

4. Conditions for the Furnishing of Samples

No provision.

EP – EUROPEAN PATENT OFFICE (EPO)

Erhardtstrasse 27
D-80298 MUNICH
Germany

Telephone: (49-89) 2399-0
Telex: 5 23 656 EPMU D
Telefax: (49-89) 2399 4465
Internet home page: <http://www.european-patent-office.org>

1. Requirements for Deposit

If an invention which is the subject of a European patent application involves the use of or concerns biological material which is not available to the public and which cannot be described in such a manner as to enable the invention to be carried out by a person skilled in the art, the applicant must make the deposit of the biological material with a recognized depositary institution.

Furthermore:

(a) the depositary institution and the accession number of the deposited biological material should be stated in the application; and

(b) where the biological material has been deposited by a person other than the applicant, the name and address of the depositor should be stated in the application and a document should be submitted satisfying the European Patent Office that the latter has authorized the applicant to refer to the deposited biological material in the application and has given his unreserved and irrevocable consent to the deposited material being made available to the public.

This information may be submitted:

(a) within a period of 16 months after the date of filing of the European patent application or, if priority is claimed, after the priority date; this time limit is deemed to have been met if the information is communicated before the technical preparations for publication of the application are completed;

(b) up to the date of submission of a request for early publication of the application;

(c) within one month after the European Patent Office has communicated to the applicant that a right to inspection of the files, pursuant to Article 128(2) EPC, exists.

The ruling period is the one which is the first to expire. The communication of this information is considered as constituting the unreserved and irrevocable consent of the applicant to the deposited biological material being made available to the public.

(Implementing Regulations to the Convention on the Grant of European Patents (EPC) of 1973, Rule 28(1), (2) as revised in 1996.)

The President of the European Patent Office publishes in the Official Journal of the European Patent Office the list of depositary institutions and experts recognized for the purpose of the European patent procedure.

(Rule 28(9))

2. Time of Deposit

A sample of the biological material should be deposited not later than the date of filing of the application.

(Rule 28(1))

Where the application claims a priority and where the invention, in order to be sufficiently disclosed, requires a deposit, that deposit must have been made not later than the date of filing of the previous application whose priority is claimed. The depositary institution and the legal status under which the biological material is deposited must comply with the requirements of the country where the previous application has been filed (Notice of the EPO, published in OJ EPO 1986, p. 269, item 8).

3. Duration of Storage

As provided for in Rule 9 of the Budapest Treaty and in point 11 of the bilateral agreements between the EPO and the depositary institutions (at least five years after the most recent request for furnishing a sample of the deposited biological material and in any case at least 30 years after the date of deposit).

4. Conditions for the Furnishing of Samples

(i) Time of Availability of Samples

The deposited biological material becomes available upon request to any person from the date of publication of the European patent application and to any person having the right to inspect the files pursuant to Article 128(2) EPC, prior to such date.

(Rule 28(3))

(ii) Restrictions Concerning the Furnishing of Samples

A sample of the deposited biological material can only be issued to the requesting party if such a party undertakes *vis-à-vis* the applicant or the patentee:

(a) not to make the deposited biological material or any biological material derived therefrom available to any third party and to use the deposited biological material or any biological material derived therefrom for experimental purposes only, until such time as the patent application is refused or withdrawn or is deemed to be withdrawn, or before the expiry of the patent in the designated State in which it last expires, unless the applicant or the patentee expressly waives such an undertaking.

The undertaking to use the biological material for experimental purposes only does not apply in so far as the requesting party is using the culture under a compulsory licence. The term “compulsory licence” includes *ex officio* licenses and the right to use patented inventions in the public interest.

(Rule 28(3))

Until completion of the technical preparations for publication of the application, the applicant may inform the European Patent Office that:

(a) until the publication of the mention of the grant of the European patent or, where applicable,

(b) for twenty years from the date of filing if the application has been refused or withdrawn or deemed to be withdrawn,

the availability of the deposited biological material is effected only by the issue of a sample to an expert nominated by the requesting party.

(Rule 28(4))

May be nominated as an expert:

(a) any natural person provided that the requesting party furnishes evidence, when filing the request, that the nomination has the approval of the applicant;

(b) any natural person recognized as an expert by the President of the European Patent Office.

The nomination must be accompanied by a declaration from the expert *vis-à-vis* the applicant in which he enters into the undertaking given pursuant to Rule 28(3) EPC until either the date on which the patent expires in all the designated States or, where the application has been refused, withdrawn or deemed to be withdrawn, until the date referred to in Rule 28(4)(b) EPC.

(Rule 28(5))

The request of a sample of the deposited biological material must be submitted to the European Patent Office on a form recognized by that Office. The European Patent Office certifies on the form that a European patent application referring to the deposit of the biological material has been filed, and that the requesting party or the expert nominated by him is entitled to the issue of a sample of that material. After grant of the European patent, the request must also be submitted to the European Patent Office.

(Rule 28(7))

The European Patent Office transmits a copy of the request, with the certification, to the depositary institution as well as to the patent applicant or the patentee.

(Rule 28(8))

[Appendix 1 follows]

**Budapest Treaty on the International
Recognition of the Deposit of Microorganisms
for the Purposes of Patent Procedure**

Done at Budapest on April 28, 1977,
and amended on September 26, 1980

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INTRODUCTORY PROVISIONS

Article 1

Establishment of a Union

The States party to this Treaty (hereinafter called “the Contracting States”) constitute a Union for the international recognition of the deposit of microorganisms for the purposes of patent procedure.

* This Table of Contents is added for the convenience of the reader. It does not appear in the original (English) text of the Treaty.

Article 2

Definitions

For the purposes of this Treaty and the Regulations:

- (i) references to a “patent” shall be construed as references to patents for inventions, inventors' certificates, utility certificates, utility models, patents or certificates of addition, inventors' certificates of addition, and utility certificates of addition;
- (ii) “deposit of a microorganism” means, according to the context in which these words appear, the following acts effected in accordance with this Treaty and the Regulations; the transmittal of a microorganism to an international depositary authority, which receives and accepts it, or the storage of such a microorganism by the international depositary authority, or both the said transmittal and the said storage;
- (iii) “patent procedure” means any administrative or judicial procedure relating to a patent application or a patent;
- (iv) “publication for the purposes of patent procedure” means the official publication, or the official laying open for public inspection, of a patent application or a patent;
- (v) “intergovernmental industrial property organization” means an organization that has filed a declaration under Article 9(1);
- (vi) “industrial property office” means an authority of a Contracting State or an intergovernmental industrial property organization competent for the grant of patents;
- (vii) “depositary institution” means an institution which provides for the receipt, acceptance and storage of microorganisms and the furnishing of samples thereof;
- (viii) “international depositary authority” means a depositary institution which has acquired the status of international depositary authority as provided in Article 7;
- (ix) “depositor” means the natural person or legal entity transmitting a microorganism to an international depositary authority, which receives and accepts it, and any successor in title of the said natural person or legal entity;
- (x) “Union” means the Union referred to in Article 1;
- (xi) “Assembly” means the Assembly referred to in Article 10;
- (xii) “Organization” means the World Intellectual Property Organization;
- (xiii) “International Bureau” means the International Bureau of the Organization and, as long as it subsists, the United International Bureaux for the Protection of Intellectual Property (BIRPI);
- (xiv) “Director General” means the Director General of the Organization;
- (xv) “Regulations” means the Regulations referred to in Article 12.

CHAPTER I

SUBSTANTIVE PROVISIONS

Article 3

Recognition and Effect of the Deposit
of Microorganisms

(1)(a) Contracting States which allow or require the deposit of microorganisms for the purposes of patent procedure shall recognize, for such purposes, the deposit of a microorganism with any international depositary authority. Such recognition shall include the recognition of the fact and date of the deposit as indicated by the international depositary authority as well as the recognition of the fact that what is furnished as a sample is a sample of the deposited microorganism.

(b) Any Contracting State may require a copy of the receipt of the deposit referred to in subparagraph (a), issued by the international depositary authority.

(2) As far as matters regulated in this Treaty and the Regulations are concerned, no Contracting State may require compliance with requirements different from or additional to those which are provided in this Treaty and the Regulations.

Article 4

New Deposit

(1)(a) Where the international depositary authority cannot furnish samples of the deposited microorganism for any reason, in particular,

- (i) where such microorganism is no longer viable, or
- (ii) where the furnishing of samples would require that they be sent abroad and the sending or the receipt of the samples abroad is prevented by export or import restrictions,

that authority shall, promptly after having noted its inability to furnish samples, notify the depositor of such inability, indicating the cause thereof, and the depositor, subject to paragraph (2) and as provided in this paragraph, shall have the right to make a new deposit of the microorganism which was originally deposited.

(b) The new deposit shall be made with the international depositary authority with which the original deposit was made, provided that:

- (i) it shall be made with another international depositary authority where the institution with which the original deposit was made has ceased to have the status of international depositary authority, either entirely or in respect of the kind of microorganism to which the deposited microorganism belongs, or where the international depositary authority with which the original deposit was made discontinues, temporarily or definitively, the performance of its functions in respect of deposited microorganisms;

(ii) it may be made with another international depositary authority in the case referred to in subparagraph (a)(ii).

(c) Any new deposit shall be accompanied by a statement signed by the depositor alleging that the newly deposited microorganism is the same as that originally deposited. If the allegation of the depositor is contested, the burden of proof shall be governed by the applicable law.

(d) Subject to subparagraphs (a) to (c) and (e), the new deposit shall be treated as if it had been made on the date on which the original deposit was made where all the preceding statements concerning the viability of the originally deposited microorganism indicated that the microorganism was viable and where the new deposit was made within three months after the date on which the depositor received the notification referred to in subparagraph (a).

(e) Where subparagraph (b)(i) applies and the depositor does not receive the notification referred to in subparagraph (a) within six months after the date on which the termination, limitation or discontinuance referred to in subparagraph (b)(i) was published by the International Bureau, the three-month time limit referred to in subparagraph (d) shall be counted from the date of the said publication.

(2) The right referred to in paragraph (1)(a) shall not exist where the deposited microorganism has been transferred to another international depositary authority as long as that authority is in a position to furnish samples of such microorganism.

Article 5

Export and Import Restrictions

Each Contracting State recognizes that it is highly desirable that, if and to the extent to which the export from or import into its territory of certain kinds of microorganisms is restricted, such restriction should apply to microorganisms deposited, or destined for deposit, under this Treaty only where the restriction is necessary in view of national security or the dangers for health or the environment.

Article 6

Status of International Depositary Authority

(1) In order to qualify for the status of international depositary authority, any depositary institution must be located on the territory of a Contracting State and must benefit from assurances furnished by that State to the effect that the said institution complies and will continue to comply with the requirements specified in paragraph (2). The said assurances may be furnished also by an intergovernmental industrial property organization; in that case, the depositary institution must be located on the territory of a State member of the said organization.

(2) The depositary institution must, in its capacity of international depositary authority:

(i) have a continuous existence;

(ii) have the necessary staff and facilities, as prescribed in the Regulations, to perform its scientific and administrative tasks under this Treaty;

- (iii) be impartial and objective;
 - (iv) be available, for the purposes of deposit, to any depositor under the same conditions;
 - (v) accept for deposit any or certain kinds of microorganisms, examine their viability and store them, as prescribed in the Regulations;
 - (vi) issue a receipt to the depositor, and any required viability statement, as prescribed in the Regulations;
 - (vii) comply, in respect of the deposited microorganisms, with the requirement of secrecy, as prescribed in the Regulations;
 - (viii) furnish samples of any deposited microorganism under the conditions and in conformity with the procedure prescribed in the Regulations.
- (3) The Regulations shall provide the measures to be taken:
- (i) where an international depositary authority discontinues, temporarily or definitively, the performance of its functions in respect of deposited microorganisms or refuses to accept any of the kinds of microorganisms which it should accept under the assurances furnished;
 - (ii) in case of the termination or limitation of the status of international depositary authority of an international depositary authority.

Article 7

Acquisition of the Status of International Depositary Authority

- (1)(a) A depositary institution shall acquire the status of international depositary authority by virtue of a written communication addressed to the Director General by the Contracting State on the territory of which the depositary institution is located and including a declaration of assurances to the effect that the said institution complies and will continue to comply with the requirements specified in Article 6(2). The said status may be acquired also by virtue of a written communication addressed to the Director General by an intergovernmental industrial property organization and including the said declaration.
- (b) The communication shall also contain information on the depositary institution as provided in the Regulations and may indicate the date on which the status of international depositary authority should take effect.
- (2)(a) If the Director General finds that the communication includes the required declaration and that all the required information has been received, the communication shall be promptly published by the International Bureau.
- (b) The status of international depositary authority shall be acquired as from the date of publication of the communication or, where a date has been indicated under paragraph (1)(b) and such date is later than the date of publication of the communication, as from such date.
- (3) The details of the procedure under paragraphs (1) and (2) are provided in the Regulations.

Article 8

Termination and Limitation of the Status
of International Depositary Authority

(1)(a) Any Contracting State or any intergovernmental industrial property organization may request the Assembly to terminate, or to limit to certain kinds of microorganisms, any authority's status of international depositary authority on the ground that the requirements specified in Article 6 have not been or are no longer complied with. However, such a request may not be made by a Contracting State or intergovernmental industrial property organization in respect of an international depositary authority for which it has made the declaration referred to in Article 7(1)(a).

(b) Before making the request under subparagraph (a), the Contracting State or the intergovernmental industrial property organization shall, through the intermediary of the Director General, notify the reasons for the proposed request to the Contracting State or the intergovernmental industrial property organization which has made the communication referred to in Article 7(1) so that that State or organization may, within six months from the date of the said notification, take appropriate action to obviate the need for making the proposed request.

(c) Where the Assembly finds that the request is well founded, it shall decide to terminate, or to limit to certain kinds of microorganisms, the status of international depositary authority of the authority referred to in subparagraph (a). The decision of the Assembly shall require that a majority of two-thirds of the votes cast be in favor of the request.

(2)(a) The Contracting State or intergovernmental industrial property organization having made the declaration referred to in Article 7(1)(a) may, by a communication addressed to the Director General, withdraw its declaration either entirely or in respect only of certain kinds of microorganisms and in any event shall do so when and to the extent that its assurances are no longer applicable.

(b) Such a communication shall, from the date provided for in the Regulations, entail, where it relates to the entire declaration, the termination of the status of international depositary authority or, where it relates only to certain kinds of microorganisms, a corresponding limitation of such status.

(3) The details of the procedure under paragraphs (1) and (2) are provided in the Regulations.

Article 9

Intergovernmental Industrial Property Organizations

(1)(a) Any intergovernmental organization to which several States have entrusted the task of granting regional patents and of which all the member States are members of the International (Paris) Union for the Protection of Industrial Property may file with the Director General a declaration that it accepts the obligation of recognition provided for in Article 3(1)(a), the obligation concerning the requirements referred to in Article 3(2) and all the effects of the provisions of this Treaty and the Regulations applicable to intergovernmental industrial property organizations. If filed before the entry into force of this Treaty according to Article 16(1), the declaration referred to in the preceding sentence shall become effective on the date of the said entry into force. If filed after such entry into force, the said declaration shall become effective three months after its filing unless a later date has been indicated in the declaration. In the latter case, the declaration shall take effect on the date thus indicated.

(b) The said organization shall have the right provided for in Article 3(1)(b).

(2) Where any provision of this Treaty or of the Regulations affecting intergovernmental industrial property organizations is revised or amended, any intergovernmental industrial property organization may withdraw its declaration referred to in paragraph (1) by notification addressed to the Director General. The withdrawal shall take effect:

(i) where the notification has been received before the date on which the revision or amendment enters into force, on that date;

(ii) where the notification has been received after the date referred to in (i), on the date indicated in the notification or, in the absence of such indication, three months after the date on which the notification was received.

(3) In addition to the case referred to in paragraph (2), any intergovernmental industrial property organization may withdraw its declaration referred to in paragraph (1)(a) by notification addressed to the Director General. The withdrawal shall take effect two years after the date on which the Director General has received the notification. No notification of withdrawal under this paragraph shall be receivable during a period of five years from the date on which the declaration took effect.

(4) The withdrawal referred to in paragraph (2) or (3) by an intergovernmental industrial property organization whose communication under Article 7(1) has led to the acquisition of the status of international depositary authority by a depositary institution shall entail the termination of such status one year after the date on which the Director General has received the notification of withdrawal.

(5) Any declaration referred to in paragraph (1)(a), notification of withdrawal referred to in paragraph (2) or (3), assurances furnished under Article 6(1), second sentence, and included in a declaration made in accordance with Article 7(1)(a), request made under Article 8(1) and communication of withdrawal referred to in Article 8(2) shall require the express previous approval of the supreme governing organ of the intergovernmental industrial property organization whose members are all the States members of the said organization and in which decisions are made by the official representatives of the governments of such States.

CHAPTER II

ADMINISTRATIVE PROVISIONS

Article 10

Assembly

(1)(a) The Assembly shall consist of the Contracting States.

(b) Each Contracting State shall be represented by one delegate, who may be assisted by alternate delegates, advisors, and experts.

(c) Each intergovernmental industrial property organization shall be represented by special observers in the meetings of the Assembly and any committee and working group established by the Assembly.

(d) Any State not member of the Union which is a member of the Organization or of the International (Paris) Union for the Protection of Industrial Property and any intergovernmental organization specialized in the field of patents other than an intergovernmental industrial property organization as defined in Article 2(v) may be represented by observers in the meetings of the Assembly and, if the Assembly so decides, in the meetings of any committee or working group established by the Assembly.

(2)(a) The Assembly shall:

(i) deal with all matters concerning the maintenance and development of the Union and the implementation of this Treaty;

(ii) exercise such rights and perform such tasks as are specially conferred upon it or assigned to it under this Treaty;

(iii) give directions to the Director General concerning the preparations for revision conferences;

(iv) review and approve the reports and activities of the Director General concerning the Union, and give him all necessary instructions concerning matters within the competence of the Union;

(v) establish such committees and working groups as it deems appropriate to facilitate the work of the Union;

(vi) determine, subject to paragraph (1)(d), which States other than Contracting States, which intergovernmental organizations other than intergovernmental industrial property organizations as defined in Article 2(v) and which international non-governmental organizations shall be admitted to its meetings as observers and to what extent international depositary authorities shall be admitted to its meetings as observers;

(vii) take any other appropriate action designed to further the objectives of the Union;

(viii) perform such other functions as are appropriate under this Treaty.

(b) With respect to matters which are of interest also to other Unions administered by the Organization, the Assembly shall make its decisions after having heard the advice of the Coordination Committee of the Organization.

(3) A delegate may represent, and vote in the name of, one State only.

(4) Each Contracting State shall have one vote.

(5)(a) One-half of the Contracting States shall constitute a quorum.

(b) In the absence of the quorum, the Assembly may make decisions but, with the exception of decisions concerning its own procedure, all such decisions shall take effect only if the quorum and the required majority are attained through voting by correspondence as provided in the Regulations.

(6)(a) Subject to Articles 8(1)(c), 12(4) and 14(2)(b), the decisions of the Assembly shall require a majority of the votes cast.

(b) Abstentions shall not be considered as votes.

(7)(a) The Assembly shall meet once in every second calendar year in ordinary session upon convocation by the Director General, preferably during the same period and at the same place as the General Assembly of the Organization.

(b) The Assembly shall meet in extraordinary session upon convocation by the Director General, either on his own initiative or at the request of one-fourth of the Contracting States.

(8) The Assembly shall adopt its own rules of procedure.

Article 11

International Bureau

(1) The International Bureau shall:

(i) perform the administrative tasks concerning the Union, in particular such tasks as are specifically assigned to it under this Treaty and the Regulations or by the Assembly;

(ii) provide the secretariat of revision conferences, of the Assembly, of committees and working groups established by the Assembly, and of any other meeting convened by the Director General and dealing with matters of concern to the Union.

(2) The Director General shall be the chief executive of the Union and shall represent the Union.

(3) The Director General shall convene all meetings dealing with matters of concern to the Union.

(4)(a) The Director General and any staff member designated by him shall participate, without the right to vote, in all meetings of the Assembly, the committees and working groups established by the Assembly, and any other meeting convened by the Director General and dealing with matters of concern to the Union.

(b) The Director General, or a staff member designated by him, shall be ex officio secretary of the Assembly, and of the committees, working groups and other meetings referred to in subparagraph (a).

(5)(a) The Director General shall, in accordance with the directions of the Assembly, make the preparations for revision conferences.

(b) The Director General may consult with intergovernmental and international non-governmental organizations concerning the preparations for revision conferences.

(c) The Director General and persons designated by him shall take part, without the right to vote, in the discussions at revision conferences.

(d) The Director General, or a staff member designated by him, shall be ex officio secretary of any revision conference.

Article 12

Regulations

- (1) The Regulations provide rules concerning:
 - (i) matters in respect of which this Treaty expressly refers to the Regulations or expressly provides that they are or shall be prescribed;
 - (ii) any administrative requirements, matters or procedures;
 - (iii) any details useful in the implementation of this Treaty.
- (2) The Regulations adopted at the same time as this Treaty are annexed to this Treaty.
- (3) The Assembly may amend the Regulations.
- (4)(a) Subject to subparagraph (b), adoption of any amendment of the Regulations shall require two-thirds of the votes cast.
- (b) Adoption of any amendment concerning the furnishing of samples of deposited microorganisms by the international depositary authorities shall require that no Contracting State vote against the proposed amendment.
- (5) In the case of conflict between the provisions of this Treaty and those of the Regulations, the provisions of this Treaty shall prevail.

CHAPTER III

REVISION AND AMENDMENT

Article 13

Revision of the Treaty

- (1) This Treaty may be revised from time to time by conferences of the Contracting States.
- (2) The convocation of any revision conference shall be decided by the Assembly.
- (3) Articles 10 and 11 may be amended either by a revision conference or according to Article 14.

Article 14

Amendment of Certain Provisions of the Treaty

- (1)(a) Proposals under this Article for the amendment of Articles 10 and 11 may be initiated by any Contracting State or by the Director General.
- (b) Such proposals shall be communicated by the Director General to the Contracting States at least six months in advance of their consideration by the Assembly.

(2)(a) Amendments to the Articles referred to in paragraph (1) shall be adopted by the Assembly.

(b) Adoption of any amendment to Article 10 shall require four-fifths of the votes cast; adoption of any amendment to Article 11 shall require three-fourths of the votes cast.

(3)(a) Any amendment to the Articles referred to in paragraph (1) shall enter into force one month after written notifications of acceptance, effected in accordance with their respective constitutional processes, have been received by the Director General from three-fourths of the Contracting States members of the Assembly at the time the Assembly adopted the amendment.

(b) Any amendment to the said Articles thus accepted shall bind all the Contracting States which were Contracting States at the time the amendment was adopted by the Assembly, provided that any amendment creating financial obligations for the said Contracting States or increasing such obligations shall bind only those Contracting States which have notified their acceptance of such amendment.

(c) Any amendment which has been accepted and which has entered into force in accordance with subparagraph (a) shall bind all States which become Contracting States after the date on which the amendment was adopted by the Assembly.

CHAPTER IV

FINAL PROVISIONS

Article 15

Becoming Party to the Treaty

(1) Any State member of the International (Paris) Union for the Protection of Industrial Property may become party to this Treaty by:

- (i) signature followed by the deposit of an instrument of ratification, or
- (ii) deposit of an instrument of accession.

(2) Instruments of ratification or accession shall be deposited with the Director General.

Article 16

Entry Into Force of the Treaty

(1) This Treaty shall enter into force, with respect to the first five States which have deposited their instruments of ratification or accession, three months after the date on which the fifth instrument of ratification or accession has been deposited.

(2) This Treaty shall enter into force with respect to any other State three months after the date on which that State has deposited its instrument of ratification or accession unless a later date has been indicated in the instrument of ratification or accession. In the latter case, this Treaty shall enter into force with respect to that State on the date thus indicated.

Article 17

Denunciation of the Treaty

- (1) Any Contracting State may denounce this Treaty by notification addressed to the Director General.
- (2) Denunciation shall take effect two years after the day on which the Director General has received the notification.
- (3) The right of denunciation provided for in paragraph (1) shall not be exercised by any Contracting State before the expiration of five years from the date on which it becomes party to this Treaty.
- (4) The denunciation of this Treaty by a Contracting State that has made a declaration referred to in Article 7(1)(a) with respect to a depositary institution which thus acquired the status of international depositary authority shall entail the termination of such status one year after the day on which the Director General received the notification referred to in paragraph (1).

Article 18

Signature and Languages of the Treaty

- (1)(a) This Treaty shall be signed in a single original in the English and French languages, both texts being equally authentic.
 - (b) Official texts of this Treaty shall be established by the Director General, after consultation with the interested Governments and within two months from the date of signature of this Treaty, in the other languages in which the Convention Establishing the World Intellectual Property Organization was signed.
 - (c) Official texts of this Treaty shall be established by the Director General, after consultation with the interested Governments, in the Arabic, German, Italian, Japanese and Portuguese languages, and such other languages as the Assembly may designate.
- (2) This Treaty shall remain open for signature at Budapest until December 31, 1977.

Article 19

Deposit of the Treaty; Transmittal of Copies;
Registration of the Treaty

- (1) The original of this Treaty, when no longer open for signature, shall be deposited with the Director General.
- (2) The Director General shall transmit two copies, certified by him, of this Treaty and the Regulations to the Governments of all the States referred to in Article 15(1), to the intergovernmental organizations that may file a declaration under Article 9(1)(a) and, on request, to the Government of any other State.

(3) The Director General shall register this Treaty with the Secretariat of the United Nations.

(4) The Director General shall transmit two copies, certified by him, of any amendment to this Treaty and to the Regulations to all Contracting States, to all intergovernmental industrial property organizations and, on request, to the Government of any other State and to any other intergovernmental organization that may file a declaration under Article 9(1)(a).

Article 20

Notifications

The Director General shall notify the Contracting States, the intergovernmental industrial property organizations and those States not members of the Union which are members of the International (Paris) Union for the Protection of Industrial Property of:

- (i) signatures under Article 18;
- (ii) deposits of instruments of ratification or accession under Article 15(2);
- (iii) declarations filed under Article 9(1)(a) and notifications of withdrawal under Article 9(2) or (3);
- (iv) the date of entry into force of this Treaty under Article 16(1);
- (v) the communications under Articles 7 and 8 and the decisions under Article 8;
- (vi) acceptance of amendments to this Treaty under Article 14(3);
- (vii) any amendment of the Regulations;
- (viii) the dates on which amendments to the Treaty or the Regulations enter into force;
- (ix) denunciations received under Article 17.

Regulations*

Under the Budapest Treaty on the International Recognition
of the Deposit of Microorganisms
for the Purposes of Patent Procedure

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* Adopted on April 28, 1977, and amended on January 20, 1981.

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Rule 1

Abbreviated Expressions and Interpretation of the Word “Signature”

1.1 “Treaty”

In these Regulations, the word “Treaty” means the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure.

1.2 “Article”

In these Regulations, the word “Article” refers to the specified Article of the Treaty.

1.3 “Signature”

In these Regulations, whenever the word “signature” is used, it shall be understood that, where the law of the State on the territory of which an international depositary authority is located requires the use of a seal instead of a signature, the said word shall mean “seal” for the purposes of that authority.

Rule 2

International Depositary Authorities

2.1 Legal Status

Any international depositary authority may be a government agency, including any public institution attached to a public administration other than the central government, or a private entity.

2.2 Staff and Facilities

The requirements referred to in Article 6(2)(ii) shall include in particular the following:

(i) the staff and facilities of any international depositary authority must enable the said authority to store the deposited microorganisms in a manner which ensures that they are kept viable and uncontaminated;

(ii) any international depositary authority must, for the storage of microorganisms, provide for sufficient safety measures to minimize the risk of losing microorganisms deposited with it.

2.3 Furnishing of Samples

The requirements referred to in Article 6(2)(viii) shall include in particular the requirement that any international depositary authority must furnish samples of deposited microorganisms in an expeditious and proper manner.

Rule 3

Acquisition of the Status of International Depositary Authority

3.1 Communication

(a) The communication referred to in Article 7(1) shall be addressed to the Director General, in the case of a Contracting State, through diplomatic channels or, in the case of an intergovernmental industrial property organization, by its chief executive officer.

(b) The communication shall:

- (i) indicate the name and address of the depositary institution to which the communication relates;
- (ii) contain detailed information as to the said institution's capacity to comply with the requirements specified in Article 6(2), including information on its legal status, scientific standing, staff and facilities;
- (iii) where the said depositary institution intends to accept for deposit only certain kinds of microorganisms, specify such kinds;
- (iv) indicate the amount of any fees that the said institution will, upon acquiring the status of international depositary authority, charge for storage, viability statements and furnishing of samples of microorganisms;
- (v) indicate the official language or languages of the said institution;
- (vi) where applicable, indicate the date referred to in Article 7(1)(b).

3.2 Processing of the Communication

If the communication complies with Article 7(1) and Rule 3.1, it shall be promptly notified by the Director General to all Contracting States and intergovernmental industrial property organizations and shall be promptly published by the International Bureau.

3.3 Extension of the List of Kinds of Microorganisms Accepted

The Contracting State or intergovernmental industrial property organization having made the communication referred to in Article 7(1) may, at any time thereafter, notify the Director General that its assurances are extended to specified kinds of microorganisms to which, so far, the assurances have not extended. In such a case, and as far as the additional kinds of microorganisms are concerned, Article 7 and Rules 3.1 and 3.2 shall apply, mutatis mutandis.

Rule 4

Termination or Limitation of the Status of International Depositary Authority

4.1 Request; Processing of Request

- (a) The request referred to in Article 8(1)(a) shall be addressed to the Director General as provided in Rule 3.1(a).
- (b) The request shall:
 - (i) indicate the name and address of the international depositary authority concerned;
 - (ii) where it relates only to certain kinds of microorganisms, specify such kinds;
 - (iii) indicate in detail the facts on which it is based.

(c) If the request complies with paragraphs (a) and (b), it shall be promptly notified by the Director General to all Contracting States and intergovernmental industrial property organizations.

(d) Subject to paragraph (e), the Assembly shall consider the request not earlier than six and not later than eight months from the notification of the request.

(e) Where, in the opinion of the Director General, respect of the time limit provided for in paragraph (d) could endanger the interests of actual or potential depositors, he may convene the Assembly for a date earlier than the date of the expiration of the six-month period provided for in paragraph (d).

(f) If the Assembly decides to terminate, or to limit to certain kinds of microorganisms, the status of international depositary authority, the said decision shall become effective three months after the date on which it was made.

4.2 Communication; Effective Date; Processing of Communication

(a) The communication referred to in Article 8(2)(a) shall be addressed to the Director General as provided in Rule 3.1(a).

(b) The communication shall:

- (i) indicate the name and address of the international depositary authority concerned;
- (ii) where it relates only to certain kinds of microorganisms, specify such kinds;
- (iii) where the Contracting State or intergovernmental industrial property organization making the communication desires that the effects provided for in Article 8(2)(b) take place on a date later than at the expiration of three months from the date of the communication, indicate that later date.

(c) Where paragraph (b)(iii) applies, the effects provided for in Article 8(2)(b) shall take place on the date indicated under that paragraph in the communication; otherwise, they shall take place at the expiration of three months from the date of the communication.

(d) The Director General shall promptly notify all Contracting States and intergovernmental industrial property organizations of any communication received under Article 8(2) and of its effective date under paragraph (c). A corresponding notice shall be promptly published by the International Bureau.

4.3 Consequences for Deposits

In the case of a termination or limitation of the status of international depositary authority under Articles 8(1), 8(2), 9(4) or 17(4), Rule 5.1 shall apply, *mutatis mutandis*.

Rule 5

Defaults by the International Depositary Authority

5.1 Discontinuance of Performance of Functions in Respect of Deposited Microorganisms

(a) If any international depositary authority temporarily or definitively discontinues the performance of any of the tasks it should perform under the Treaty and these Regulations in relation to any microorganisms deposited with it, the Contracting State or intergovernmental industrial property organization which, in respect of that authority, has furnished the assurances under Article 6(1) shall:

(i) ensure, to the fullest extent possible, that samples of all such microorganisms are transferred promptly and without deterioration or contamination from the said authority (“the defaulting authority”) to another international depositary authority (“the substitute authority”);

(ii) ensure, to the fullest extent possible, that all mail or other communications addressed to the defaulting authority, and all files and other relevant information in the possession of that authority, in respect of the said microorganisms are promptly transferred to the substitute authority;

(iii) ensure, to the fullest extent possible, that the defaulting authority promptly notifies all depositors affected of the discontinuance of the performance of its functions and the transfers effected;

(iv) promptly notify the Director General of the fact and the extent of the discontinuance in question and of the measures which have been taken by the said Contracting State or intergovernmental industrial property organization under (i) to (iii).

(b) The Director General shall promptly notify the Contracting States and the intergovernmental industrial property organizations as well as the industrial property offices of the notification received under paragraph (a)(iv); the notification of the Director General and the notification received by him shall be promptly published by the International Bureau.

(c) Under the applicable patent procedure it may be required that the depositor shall, promptly after receiving the receipt referred to in Rule 7.5, notify to any industrial property office with which a patent application was filed with reference to the original deposit the new accession number given to the deposit by the substitute authority.

(d) The substitute authority shall retain in an appropriate form the accession number given by the defaulting authority, together with the new accession number.

(e) In addition to any transfer effected under paragraph (a)(i), the defaulting authority shall, upon request by the depositor, transfer, as far as possible, a sample of any microorganism deposited with it together with copies of all mail or other communications and copies of all files and other relevant information referred to in paragraph (a)(ii) to any international depositary authority indicated by the depositor other than the substitute authority, provided that the depositor pays any expenses to the defaulting authority resulting from the said transfer. The depositor shall pay the fee for the storage of the said sample to the international depositary authority indicated by him.

(f) On the request of any depositor affected, the defaulting authority shall retain, as far as possible, samples of the microorganisms deposited with it.

5.2 Refusal To Accept Certain Kinds of Microorganisms

(a) If any international depositary authority refuses to accept for deposit any of the kinds of microorganisms which it should accept under the assurances furnished, the Contracting State or intergovernmental industrial property organization which, in respect of that authority, has made the declaration referred to in Article 7(1)(a) shall promptly notify the Director General of the relevant facts and the measures which have been taken.

(b) The Director General shall promptly notify the other Contracting States and intergovernmental industrial property organizations of the notification received under paragraph (a); the notification of the Director General and the notification received by him shall be promptly published by the International Bureau.

Rule 6

Making the Original Deposit or New Deposit

6.1 Original Deposit

(a) The microorganism transmitted by the depositor to the international depositary authority shall, except where Rule 6.2 applies, be accompanied by a written statement bearing the signature of the depositor and containing:

(i) an indication that the deposit is made under the Treaty and an undertaking not to withdraw it for the period specified in Rule 9.1;

(ii) the name and address of the depositor;

(iii) details of the conditions necessary for the cultivation of the microorganism, for its storage and for testing its viability and also, where a mixture of microorganisms is deposited, descriptions of the components of the mixture and at least one of the methods permitting the checking of their presence;

(iv) an identification reference (number, symbols, etc.) given by the depositor to the microorganism;

(v) an indication of the properties of the microorganism which are or may be dangerous to health or the environment, or an indication that the depositor is not aware of such properties.

(b) It is strongly recommended that the written statement referred to in paragraph (a) should contain the scientific description and/or proposed taxonomic designation of the deposited microorganism.

6.2 New Deposit

(a) Subject to paragraph (b), in the case of a new deposit made under Article 4, the microorganism transmitted by the depositor to the international depositary authority shall be accompanied by a copy of the receipt of the previous deposit, a copy of the most recent statement concerning the viability of the microorganism which was the subject of the previous deposit indicating that the microorganism is viable and a written statement bearing the signature of the depositor and containing:

(i) the indications referred to in Rule 6.1(a)(i) to (v);

(ii) a declaration stating the reason relevant under Article 4(1)(a) for making the new deposit, a statement alleging that the microorganism which is the subject of the new deposit is the same as that which was the subject of the previous deposit, and an indication of the date on which the depositor received the notification referred to in Article 4(1)(a) or, as the case may be, the date of the publication referred to in Article 4(1)(e);

(iii) where a scientific description and/or proposed taxonomic designation was/were indicated in connection with the previous deposit, the most recent scientific description and/or proposed taxonomic designation as communicated to the international depositary authority with which the previous deposit was made.

(b) Where the new deposit is made with the international depositary authority with which the previous deposit was made, paragraph (a)(i) shall not apply.

(c) For the purposes of paragraphs (a) and (b) and of Rule 7.4, “previous deposit” means,

(i) where the new deposit has been preceded by one or more other new deposits: the most recent of those other new deposits;

(ii) where the new deposit has not been preceded by one or more other new deposits: the original deposit.

6.3 Requirements of the International Depositary Authority

(a) Any international depositary authority may require:

(i) that the microorganism be deposited in the form and quantity necessary for the purposes of the Treaty and these Regulations;

(ii) that a form established by such authority and duly completed by the depositor for the purposes of the administrative procedures of such authority be furnished;

(iii) that the written statement referred to in Rule 6.1(a) or 6.2(a) be drafted in the language, or in any of the languages, specified by such authority, it being understood that such specification must at least include the official language or languages indicated under Rule 3.1(b)(v);

(iv) that the fee for storage referred to in Rule 12.1(a)(i) be paid; and

(v) that, to the extent permitted by the applicable law, the depositor enter into a contract with such authority defining the liabilities of the depositor and the said authority.

(b) Any international depositary authority shall communicate any such requirements and any amendments thereof to the International Bureau.

6.4 Acceptance Procedure

(a) The international depositary authority shall refuse to accept the microorganism and shall immediately notify the depositor in writing of such refusal and of the reasons therefor:

(i) where the microorganism is not of a kind of microorganism to which the assurances furnished under Rule 3.1(b)(iii) or 3.3 extend;

(ii) where the properties of the microorganism are so exceptional that the international depositary authority is technically not in a position to perform the tasks in relation to it that it must perform under the Treaty and these Regulations;

(iii) where the deposit is received in a condition which clearly indicates that the microorganism is missing or which precludes for scientific reasons the acceptance of the microorganism.

(b) Subject to paragraph (a), the international depositary authority shall accept the microorganism when all the requirements of Rule 6.1(a) or 6.2(a) and Rule 6.3(a) are complied with. If any of those requirements are not complied with, the international depositary authority shall immediately notify the depositor in writing of that fact and invite him to comply with those requirements.

(c) When the microorganism has been accepted as an original or new deposit, the date of that original or new deposit, as the case may be, shall be the date on which the microorganism was received by the international depositary authority.

(d) The international depositary authority shall, on the request of the depositor and provided that all the requirements referred to in paragraph (b) are complied with, consider a microorganism, deposited before the acquisition by such authority of the status of international depositary authority, to have been received, for the purposes of the Treaty, on the date on which such status was acquired.

Rule 7

Receipt

7.1 Issuance of Receipt

The international depositary authority shall issue to the depositor, in respect of each deposit of microorganism effected with it or transferred to it, a receipt in attestation of the fact that it has received and accepted the microorganism.

7.2 Form; Languages; Signature

(a) Any receipt referred to in Rule 7.1 shall be established on a form called an “international form,” a model of which shall be established by the Director General in those languages which the Assembly shall designate.

(b) Any words or letters filled in in the receipt in characters other than those of the Latin alphabet shall also appear therein transliterated in characters of the Latin alphabet.

(c) The receipt shall bear the signature of the person or persons having the power to represent the international depositary authority or that of any other official of that authority duly authorized by the said person or persons.

7.3 Contents in the Case of the Original Deposit

Any receipt referred to in Rule 7.1 and issued in the case of an original deposit shall indicate that it is issued by the depositary institution in its capacity of international depositary authority under the Treaty and shall contain at least the following indications:

- (i) the name and address of the international depositary authority;
- (ii) the name and address of the depositor;

- (iii) the date of the original deposit as defined in Rule 6.4(c);
- (iv) the identification reference (number, symbols, etc.) given by the depositor to the microorganism;
- (v) the accession number given by the international depositary authority to the deposit;
- (vi) where the written statement referred to in Rule 6.1(a) contains the scientific description and/or proposed taxonomic designation of the microorganism, a reference to that fact.

7.4 Contents in the Case of the New Deposit

Any receipt referred to in Rule 7.1 and issued in the case of a new deposit effected under Article 4 shall be accompanied by a copy of the receipt of the previous deposit (within the meaning of Rule 6.2(c)) and a copy of the most recent statement concerning the viability of the microorganism which was the subject of the previous deposit (within the meaning of Rule 6.2(c)) indicating that the microorganism is viable, and shall at least contain:

- (i) the name and address of the international depositary authority;
- (ii) the name and address of the depositor;
- (iii) the date of the new deposit as defined in Rule 6.4(c);
- (iv) the identification reference (number, symbols, etc.) given by the depositor to the microorganism;
- (v) the accession number given by the international depositary authority to the new deposit;
- (vi) an indication of the relevant reason and the relevant date as stated by the depositor in accordance with Rule 6.2(a)(ii);
- (vii) where Rule 6.2(a)(iii) applies, a reference to the fact that a scientific description and/or a proposed taxonomic designation has/have been indicated by the depositor;
- (viii) the accession number given to the previous deposit (within the meaning of Rule 6.2(c)).

7.5 Receipt in the Case of Transfer

The international depositary authority to which samples of microorganisms are transferred under Rule 5.1(a)(i) shall issue to the depositor, in respect of each deposit in relation with which a sample is transferred, a receipt indicating that it is issued by the depositary institution in its capacity of international depositary authority under the Treaty and containing at least:

- (i) the name and address of the international depositary authority;
- (ii) the name and address of the depositor;
- (iii) the date on which the transferred sample was received by the international depositary authority (date of the transfer);

(iv) the identification reference (number, symbols, etc.) given by the depositor to the microorganism;

(v) the accession number given by the international depositary authority;

(vi) the name and address of the international depositary authority from which the transfer was effected;

(vii) the accession number given by the international depositary authority from which the transfer was effected;

(viii) where the written statement referred to in Rule 6.1(a) or 6.2(a) contained the scientific description and/or proposed taxonomic designation of the microorganism, or where such scientific description and/or proposed taxonomic designation was/were indicated or amended under Rule 8.1 at a later date, a reference to that fact.

7.6 Communication of the Scientific Description and/or Proposed Taxonomic Designation

On request of any party entitled to receive a sample of the deposited microorganism under Rules 11.1, 11.2 or 11.3, the international depositary authority shall communicate to such party the most recent scientific description and/or proposed taxonomic designation referred to in Rules 6.1(b), 6.2(a)(iii) or 8.1(b)(iii).

Rule 8

Later Indication or Amendment of the Scientific Description and/or Proposed Taxonomic Designation

8.1 Communication

(a) Where, in connection with the deposit of a microorganism, the scientific description and/or taxonomic designation of the microorganism was/were not indicated, the depositor may later indicate or, where already indicated, may amend such description and/or designation.

(b) Any such later indication or amendment shall be made in a written communication, bearing the signature of the depositor, addressed to the international depositary authority and containing:

(i) the name and address of the depositor;

(ii) the accession number given by the said authority;

(iii) the scientific description and/or proposed taxonomic designation of the microorganism;

(iv) in the case of an amendment, the last preceding scientific description and/or proposed taxonomic designation.

8.2 Attestation

The international depositary authority shall, on the request of the depositor having made the communication referred to in Rule 8.1, deliver to him an attestation showing the data referred to in Rule 8.1(b)(i) to (iv) and the date of receipt of such communication.

Rule 9

Storage of Microorganisms

9.1 Duration of the Storage

Any microorganism deposited with an international depositary authority shall be stored by such authority, with all the care necessary to keep it viable and uncontaminated, for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism was received by the said authority and, in any case, for a period of at least 30 years after the date of the deposit.

9.2 Secrecy

No international depositary authority shall give information to anyone whether a microorganism has been deposited with it under the Treaty. Furthermore, it shall not give any information to anyone concerning any microorganism deposited with it under the Treaty except to an authority, natural person or legal entity which is entitled to obtain a sample of the said microorganism under Rule 11 and subject to the same conditions as provided in that Rule.

Rule 10

Viability Test and Statement

10.1 Obligation to Test

The international depositary authority shall test the viability of each microorganism deposited with it:

- (i) promptly after any deposit referred to in Rule 6 or any transfer referred to in Rule 5.1;
- (ii) at reasonable intervals, depending on the kind of microorganism and its possible storage conditions, or at any time, if necessary for technical reasons;
- (iii) at any time, on the request of the depositor.

10.2 Viability Statement

(a) The international depositary authority shall issue a statement concerning the viability of the deposited microorganism:

- (i) to the depositor, promptly after any deposit referred to in Rule 6 or any transfer referred to in Rule 5.1;
- (ii) to the depositor, on his request, at any time after the deposit or transfer;

(iii) to any industrial property office, other authority, natural person or legal entity, other than the depositor, to whom or to which samples of the deposited microorganism were furnished in conformity with Rule 11, on his or its request, together with or at any time after such furnishing of samples.

(b) The viability statement shall indicate whether the microorganism is or is no longer viable and shall contain:

- (i) the name and address of the international depositary authority issuing it;
- (ii) the name and address of the depositor;
- (iii) the date referred to in Rule 7.3(iii) or, where a new deposit or a transfer has been made, the most recent of the dates referred to in Rules 7.4(iii) and 7.5(iii);
- (iv) the accession number given by the said authority;
- (v) the date of the test to which it refers;
- (vi) information on the conditions under which the viability test has been performed, provided that the said information has been requested by the party to which the viability statement is issued and that the results of the test were negative.

(c) In the cases of paragraph (a)(ii) and (iii), the viability statement shall refer to the most recent viability test.

(d) As to form, languages and signature, Rule 7.2 shall apply, mutatis mutandis, to the viability statement.

(e) In the case of paragraph (a)(i) or where the request is made by an industrial property office, the issuance of the viability statement shall be free of charge. Any fee payable under Rule 12.1(a)(iii) in respect of any other viability statement shall be chargeable to the party requesting the statement and shall be paid before or at the time of making the request.

Rule 11

Furnishing of Samples

11.1 Furnishing of Samples to Interested Industrial Property Offices

Any international depositary authority shall furnish a sample of any deposited microorganism to the industrial property office of any Contracting State or of any intergovernmental industrial property organization, on the request of such office, provided that the request shall be accompanied by a declaration to the effect that:

- (i) an application referring to the deposit of that microorganism has been filed with that office for the grant of a patent and that the subject matter of that application involves the said microorganism or the use thereof;
- (ii) such application is pending before that office or has led to the grant of a patent;

(iii) the sample is needed for the purposes of a patent procedure having effect in the said Contracting State or in the said organization or its member States;

(iv) the said sample and any information accompanying or resulting from it will be used only for the purposes of the said patent procedure.

11.2 Furnishing of Samples to or with the Authorization of the Depositor

Any international depositary authority shall furnish a sample of any deposited microorganism:

(i) to the depositor, on his request;

(ii) to any authority, natural person or legal entity (hereinafter referred to as “the authorized party”), on the request of such party, provided that the request is accompanied by a declaration of the depositor authorizing the requested furnishing of a sample.

11.3 Furnishing of Samples to Parties Legally Entitled

(a) Any international depositary authority shall furnish a sample of any deposited microorganism to any authority, natural person or legal entity (hereinafter referred to as “the certified party”), on the request of such party, provided that the request is made on a form whose contents are fixed by the Assembly and that on the said form the industrial property office certifies:

(i) that an application referring to the deposit of that microorganism has been filed with that office for the grant of a patent and that the subject matter of that application involves the said microorganism or the use thereof;

(ii) that, except where the second phrase of (iii) applies, publication for the purposes of patent procedure has been effected by that office;

(iii) either that the certified party has a right to a sample of the microorganism under the law governing patent procedure before that office and, where the said law makes the said right dependent on the fulfillment of certain conditions, that that office is satisfied that such conditions have actually been fulfilled or that the certified party has affixed his signature on a form before that office and that, as a consequence of the signature of the said form, the conditions for furnishing a sample to the certified party are deemed to be fulfilled in accordance with the law governing patent procedure before that office; where the certified party has the said right under the said law prior to publication for the purposes of patent procedure by the said office and such publication has not yet been effected, the certification shall expressly state so and shall indicate, by citing it in the customary manner, the applicable provision of the said law, including any court decision.

(b) In respect of patents granted and published by any industrial property office, such office may from time to time communicate to any international depositary authority lists of the accession numbers given by that authority to the deposits of the microorganisms referred to in the said patents. The international depositary authority shall, on the request of any authority, natural person or legal entity (hereinafter referred to as “the requesting party”), furnish to it a sample of any microorganism where the accession number has been so communicated. In respect of deposited microorganisms whose accession numbers have been so communicated, the said office shall not be required to provide the certification referred to in Rule 11.3(a).

11.4 Common Rules

(a) Any request, declaration, certification or communication referred to in Rules 11.1, 11.2 and 11.3 shall be

(i) in English, French, Russian or Spanish where it is addressed to an international depositary authority whose official language is or whose official languages include English, French, Russian or Spanish, respectively, provided that, where it must be in Russian or Spanish, it may be instead filed in English or French and, if it is so filed, the International Bureau shall, on the request of the interested party referred to in the said Rules or the international depositary authority, establish, promptly and free of charge, a certified translation into Russian or Spanish;

(ii) in all other cases, it shall be in English or French, provided that it may be, instead, in the official language or one of the official languages of the international depositary authority.

(b) Notwithstanding paragraph (a), where the request referred to in Rule 11.1 is made by an industrial property office whose official language is Russian or Spanish, the said request may be in Russian or Spanish, respectively, and the International Bureau shall establish, promptly and free of charge, a certified translation into English or French, on the request of that office or the international depositary authority which received the said request.

(c) Any request, declaration, certification or communication referred to in Rules 11.1, 11.2 and 11.3 shall be in writing, shall bear a signature and shall be dated.

(d) Any request, declaration or certification referred to in Rules 11.1, 11.2 and 11.3(a) shall contain the following indications:

(i) the name and address of the industrial property office making the request, of the authorized party or of the certified party, as the case may be;

(ii) the accession number given to the deposit;

(iii) in the case of Rule 11.1, the date and number of the application or patent referring to the deposit;

(iv) in the case of Rule 11.3(a), the indications referred to in (iii) and the name and address of the industrial property office which has made the certification referred to in the said Rule.

(e) Any request referred to in Rule 11.3(b) shall contain the following indications:

(i) the name and address of the requesting party;

(ii) the accession number given to the deposit.

(f) The container in which the sample furnished is placed shall be marked by the international depositary authority with the accession number given to the deposit and shall be accompanied by a copy of the receipt referred to in Rule 7, an indication of any properties of the microorganism which are or may be dangerous to health or the environment and, upon request, an indication of the conditions which the international depositary authority employs for the cultivation and storage of the microorganism.

(g) The international depositary authority having furnished a sample to any interested party other than the depositor shall promptly notify the depositor in writing of that fact, as well as of the date on which the said sample was furnished and of the name and address of the industrial property office, of the authorized party, of the certified party or of the requesting party, to whom or to which the sample was furnished. The said notification shall be accompanied by a copy of the pertinent request, of any declarations submitted under Rules 11.1 or 11.2(ii) in connection with the said request, and of any forms or requests bearing the signature of the requesting party in accordance with Rule 11.3.

(h) The furnishing of samples referred to in Rule 11.1 shall be free of charge. Where the furnishing of samples is made under Rule 11.2 or 11.3, any fee payable under Rule 12.1(a)(iv) shall be chargeable to the depositor, to the authorized party, to the certified party or to the requesting party, as the case may be, and shall be paid before or at the time of making the said request.

11.5 Changes in Rules 11.1 and 11.3 when Applying to International Applications

Where an application was filed as an international application under the Patent Cooperation Treaty, the reference to the filing of the application with the industrial property office in Rules 11.1(i) and 11.3(a)(i) shall be considered a reference to the designation, in the international application, of the Contracting State for which the industrial property office is the “designated Office” within the meaning of that Treaty, and the certification of publication which is required by Rule 11.3(a)(ii) shall, at the option of the industrial property office, be either a certification of international publication under the said Treaty or a certification of publication by the industrial property office.

Rule 12

Fees

12.1 Kinds and Amounts

(a) Any international depositary authority may, with respect to the procedure under the Treaty and these Regulations, charge a fee:

- (i) for storage;
- (ii) for the attestation referred to in Rule 8.2;
- (iii) subject to Rule 10.2(e), first sentence, for the issuance of viability statements;
- (iv) subject to Rule 11.4(h), first sentence, for the furnishing of samples;
- (v) for the communication of information under Rule 7.6.

(b) The fee for storage shall be for the whole duration of the storage of the microorganism as provided in Rule 9.1.

(c) The amount of any fee shall not vary on account of the nationality or residence of the depositor or on account of the nationality or residence of the authority, natural person or legal entity requesting the issuance of a viability statement or furnishing of samples.

12.2 Change in the Amounts

(a) Any change in the amount of the fees charged by any international depositary authority shall be notified to the Director General by the Contracting State or intergovernmental industrial property organization which made the declaration referred to in Article 7(1) in respect of that authority. The notification may, subject to paragraph (c), contain an indication of the date from which the new fees will apply.

(b) The Director General shall promptly notify all Contracting States and intergovernmental industrial property organizations of any notification received under paragraph (a) and of its effective date under paragraph (c); the notification of the Director General and the notification received by him shall be promptly published by the International Bureau.

(c) Any new fees shall apply as of the date indicated under paragraph (a), provided that, where the change consists of an increase in the amounts of the fees or where no date is so indicated, the new fees shall apply as from the thirtieth day following the publication of the change by the International Bureau.

Rule 12bis

Computation of Time Limits

12bis.1 Periods Expressed in Years

When a period is expressed as one year or a certain number of years, computation shall start on the day following the day on which the relevant event occurred, and the period shall expire in the relevant subsequent year in the month having the same name and on the day having the same number as the month and the day on which the said event occurred, provided that if the relevant subsequent month has no day with the same number the period shall expire on the last day of that month.

12bis.2 Periods Expressed in Months

When a period is expressed as one month or a certain number of months, computation shall start on the day following the day on which the relevant event occurred, and the period shall expire in the relevant subsequent month on the day which has the same number as the day on which the said event occurred, provided that if the relevant subsequent month has no day with the same number the period shall expire on the last day of that month.

12bis.3 Periods Expressed in Days

When a period is expressed as a certain number of days, computation shall start on the day following the day on which the relevant event occurred, and the period shall expire on the day on which the last day of the count has been reached.

Rule 13

Publication by the International Bureau

13.1 Form of Publication

Any publication by the International Bureau referred to in the Treaty or these Regulations shall be made in the monthly periodical of the International Bureau referred to in the Paris Convention for the Protection of Industrial Property.

13.2 Contents

(a) At least in the first issue of each year of the said periodical, an up-to-date list of the international depositary authorities shall be published, indicating in respect of each such authority the kinds of microorganisms that may be deposited with it and the amount of the fees charged by it.

(b) Full information on any of the following facts shall be published once, in the first issue of the said periodical published after the occurrence of the fact:

(i) any acquisition, termination or limitation of the status of international depositary authority, and the measures taken in connection with that termination or limitation;

(ii) any extension referred to in Rule 3.3;

(iii) any discontinuance of the functions of an international depositary authority, any refusal to accept certain kinds of microorganisms, and the measures taken in connection with such discontinuance or refusal;

(iv) any change in the fees charged by an international depositary authority;

(v) any requirements communicated in accordance with Rule 6.3(b) and any amendments thereof.

Rule 14

Expenses of Delegations

14.1 Coverage of Expenses

The expenses of each delegation participating in any session of the Assembly and in any committee, working group or other meeting dealing with matters of concern to the Union shall be borne by the State or organization which has appointed it.

Rule 15

Absence of Quorum in the Assembly

15.1 Voting by Correspondence

(a) In the case provided for in Article 10(5)(b), the Director General shall communicate any decision of the Assembly (other than decisions relating to the Assembly's own procedure) to the

Contracting States which were not represented when the decision was made and shall invite them to express in writing their vote or abstention within a period of three months from the date of the communication.

(b) If, at the expiration of the said period, the number of Contracting States having thus expressed their vote or abstention attains the number of Contracting States which was lacking for attaining the quorum when the decision was made, that decision shall take effect provided that at the same time the required majority still obtains.

[Appendix 3 follows]

CHECKLISTS OF POINTS TO BE ATTENDED TO WHEN
DEPOSITING MICROORGANISMS AND
REQUESTING SAMPLES UNDER THE BUDAPEST TREATY

The purpose of these checklists is to enable depositors and requesting parties to see at a glance whether they have omitted any essential step in making a deposit or asking for a sample of a microorganism, as the case may be. The points on the checklists are intentionally brief and the main body of the Guide should be consulted as necessary for more detailed information, explanation and/or discussion. To facilitate this, each point on the checklists is followed by reference to those sections or paragraphs of the Guide where more detailed information may be found and, where relevant, to the pertinent provisions of the Treaty itself.

Checklists for Depositors

(a) Making the Original Deposit (Section A)

- (i) Check the latest date by which deposit must be made (Section E).
- (ii) Start the deposit procedure in good time (43 to 49; 53).
- (iii) Check that the IDA can accept your microorganism (25 and 26; 49; 54; Section D; Rule 6.4(a)(i) and (ii)).
- (iv) Check the requirements of the IDA (17 to 22; 55; 59; Section D; Rule 6.3(a)).
- (v) Ask for the appropriate forms (18; 55; Section D; Appendix 3; Rule 6.3(a)(ii)).
- (vi) Complete the forms fully and correctly and sign them (11 to 15; 56; Rule 6.1(a)).
- (vii) Make it clear to whom the IDA should send official communications (50; 57; Rules 7; 10; 11.4(g); Article 4(1)(a); Rule 5.1(a)(iii)).
- (viii) Give the name and address of your patent agent and state if he should receive copies of the receipt and viability statement (50; 58; Rules 7; 10).
- (ix) Ensure your microorganism is in the form and quantity required by the IDA (17; 59; Section D; Rule 6.3(a)(i)).
- (x) Ensure your microorganism is correctly packaged (27; 46; Appendix 4; Rule 6.4(a)(iii)).
- (xi) Do not lose the receipt and/or viability statement (32 to 39; 63).
- (xii) Test promptly any preparations the IDA sends for authenticity checking (62; Section D).

- (xiii) If you are converting an existing deposit into a Budapest deposit, attend to points (iv) to (viii) and (xi) and (xii), above (30; 31; 64; Rule 6.4(d)).
- (xiv) If, despite the exhortations in the Guide, you have left making a deposit until the last minute, give priority to sending the microorganism itself to the IDA (29; 61; Rule 6.4(c)).

(b) Making a New Deposit (Section B)

- (i) Note the date on which you received notification from the IDA of its inability to furnish samples, and the reason for such inability (65; 77; Article 4(1)(a)).
- (ii) Calculate the latest date by which your new deposit must be made (67 to 69; 77; Article 4(1)(d)).
- (iii) Start the deposit procedure in good time (43 to 49; 75).
- (iv) If the reason in (i), above, is discontinuance or loss of status, ask the IDA if your deposits will be transferred to a substitute IDA under Rule 5.1(a)(i) (69; 77; 83; 84; 86; Rule 5).
- (v) If the answer to (iv), above, is YES, then you do not have the right to make a new deposit (66; Article 4(2)).
- (vi) If the answer to (iv), above, is NO, or if import/export restrictions make a new deposit with another IDA necessary (65; Article 4(1)(b)(i) and (ii)), check that the IDA you select can accept your microorganism (79; Section D; Rule 6.4(a)(i) and (ii)).
- (vii) Check the requirements of the IDA (79; Rule 6.3(a)).
- (viii) If you are making a new deposit with another IDA or with the original IDA, ask for the appropriate forms for making a new deposit under Article 4 (18; 55; Section D; Appendix 3).
- (ix) Complete the forms fully and correctly and sign them (11 to 15; 56; 66; Rules 6.1(a) and 6.2(a) and (b)).
- (x) Unless the forms provide space for it, ensure that you append a signed statement giving:
 - the reason for making a new deposit;
 - the date on which you received notification from the IDA of its inability to furnish samples; and
 - a declaration that the microorganism you are submitting is the same as that previously deposited (66; 81; Article 4(1)(c); Rule 6.2(a)(ii)).

- (xi) Ensure that you enclose with the forms and statement copies of the receipt, the latest viability statement and, where applicable, the latest scientific description/taxonomic designation in respect of the previous deposit (66; 82; Rule 6.2(a)).
- (xii) Attend to points (vii) to (xii) and (xiv) of checklist (a), above.

Checklists for Requesting Parties (Section C)

In all cases, before requesting a sample, ensure that you have complied with any import, quarantine, health and safety, etc., requirements (106).

- (a) Requesting a Sample with the Authorization for the Depositor (90; 93; 94; 101; Rules 11.2(ii) and 11.4(a), (c) and (d)(i) and (ii))

Attempt this route to obtaining a sample only if you know the identity of the depositor, in which case either:

- (i) ask the IDA for WIPO model form BP/11, if it keeps copies of this form (Section D; Appendix 3); and
 - (ii) complete parts I, III and IV of the form, then send it to the depositor asking him to complete part II; or
 - (iii) write to the depositor asking him for an appropriate declaration of authorization (90; 101; Rule 11.4(a), (c) and (d) (i) and (ii)).
 - (iv) send completed form BP/11 or the depositor's declaration, as the case may be, to the IDA together with your request and purchase order.
 - (v) When requested, pay the fee charged by the IDA for furnishing the sample (97; Rule 12.1(a)(iv)).
- (b) Requesting A Sample with Industrial Property Office Certification (91; 93; 94; 102; 103; Rules 11.3(a) and 11.4(a), (c) and (d))
 - (i) Ask the industrial property office or the IDA for the appropriate form (Section E; Appendix 3).
 - (ii) Complete that part of the form to be filled in by "the requesting party."
 - (iii) Send the form to the industrial property office (Section E).
 - (iv) When the form, endorsed by the industrial property office, is returned, send it and any certificate to the IDA together with a purchase order.
 - (v) When requested, pay the fee charged by the IDA for furnishing the sample (97; Rule 12.1(a)(iv)).

(c) Requesting a Sample of an Unrestricted Deposit (92 to 94; 105; Rules 11.3(b) and 11.4(a), (c) and (e))

To request a sample of a microorganism which is the subject of a granted and published patent, which is available without the need for certification, and of which the accession number has been communicated by the industrial property office to the IDA:

- (i) write to the IDA with purchase order giving your name and address and quoting the accession number of the microorganism (105; Rule 11.3(b)).
- (ii) When requested, pay the fee charged by the IDA for the furnishing of the sample (97; Rule 12.1(a)(iv)).

(d) Requesting a Sample of a Microorganism which is the Subject of a Published US patent (92 to 94; 104)

- (i) Ask the IDA if it is aware that the relevant US patent has issued (92; 104).
- (ii) If the answer to (i), above, is YES, proceed as in (c), above.
- (iii) If the answer to (i), above, is NO, include with your request and purchase order evidence of the publication of the relevant US patent (92; 104).
- (iv) If you cannot comply with (iii), above, expect a delay until the IDA has verified the fact of publication (92).
- (v) When asked, pay the fee charged by the IDA for the furnishing of the sample (97; Rule 12.1(a)(iv)).

[Appendix 2 follows]

REQUIRED STANDARDS OF PACKAGING FOR THE TRANSPORT OF MICROORGANISMS BY AIR*

1. General

If cultures of microorganisms are to be transported by air, they must be packaged and identified by display labelling and certification in such a way as to satisfy the regulations of the International Air Transport Association (IATA) for the shipping of perishable biological substances. These regulations apply whether the microorganisms are to be sent by air freight or by air mail, and packages not complying are liable to be refused transit by the carrier or to be stopped and destroyed by customs or postal authorities.

This Appendix is intended only as a general guide to the required standards of packaging for the transport of microorganisms by air. The actual regulations themselves are updated regularly by IATA and there are slight variations in the detailed requirements of individual air operators and of individual countries. Therefore, senders should check with their own freight handling agents and/or postal authorities as appropriate for exact and up-to-date information.

2. Categorization of Microorganisms

For the purposes of air transport regulations, microorganisms fall into two broad categories, depending on their pathogenicity: infectious substances (infectious perishable biological substances or IPBS) and non-infectious substances (non-infectious perishable biological substances or non-infectious PBS).

3. Infectious Substances**

(a) Definition

Infectious substances are subject to the IATA Dangerous Goods Regulations and are defined therein as:

“substances containing viable microorganisms or their toxins which are known, or suspected, to cause disease in animals or humans.”

*

This Appendix takes into account information contained in the brochure “Shipping of Infectious, Non-Infectious and Genetically Modified Biological Material – International Regulations,” edited by the Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH (DSMZ), Braunschweig, Germany.

**

Much of the information relating to the transport of infectious substances has been taken directly from the IATA Dangerous Goods Regulations by kind permission of the International Air Transport Association, Montreal, Canada.

(b) Packaging

Packages containing infectious substances must comply both with the IATA General Packing Requirements, which apply to all dangerous goods, and with the specific requirements for packing infectious substances. The General Packing Requirements, which include details of the minimum specifications and tolerances of packaging systems and materials, are given in paragraphs 5.0.8 to 5.0.23 of the IATA Dangerous Goods Regulations. These requirements are intended to ensure, inter alia, that packages and their closures will withstand the normal stresses of air transport (vibration, changes in pressure, temperature, humidity, etc.) without leakage; that they are not affected chemically or physically by their contents; that materials which react dangerously with each other are not packaged together; and that infectious substances are packaged separately from other dangerous goods.

The specific requirements for the packaging of infectious substances are laid down in Packing Instruction 602 of the IATA Dangerous Goods Regulations. Shipments must be packaged so that they arrive at their destination in good condition and do not present any hazard to humans or animals during transit. Packaging must include the following elements:

- (i) Inner packagings comprising:
 - a watertight primary receptacle (culture vessel);
 - a watertight secondary packaging;
 - an absorbent material which must be placed between the primary receptacle and the secondary packaging. If several primary receptacles are placed in a single secondary packaging they must be wrapped individually to ensure that contact between them is prevented. The absorbent material (e.g., cotton wool, cellulose wadding, etc.) must be sufficient to absorb the entire contents of all primary receptacles.
- (ii) An outer packaging of sufficient strength to meet the performance tests specified by the IATA Regulations. These tests are designed to ensure that the package will withstand the stresses of normal handling during transit and will not be damaged by accidental dropping, crushing, etc.

Packages sent as air freight must be at least 100mm in the smallest overall external dimension.

All packages containing infectious substances must contain, between the secondary and outer packagings, an itemized list of contents and must be accompanied by two copies of the IATA Shipper's Declaration for dangerous goods, made out on the official IATA form which can be obtained from freight agents.

With a few exceptions, infectious substances can and must be packaged according to the following guidelines:

(c) Lyophilized Substances

Primary receptacles include flame-sealed glass ampoules or rubber stoppered glass vials fitted with metal seals. Dried or freeze-dried non-infectious microbial cultures may not be considered to be perishable. Therefore, such cultures may be shipped by mail to any country as far as no general import restrictions exist. Infectious, non-perishable cultures, however, should be handled in any case like infectious perishable microbial cultures.

(d) Liquid or Solid Substances

(i) Shipped at Ambient Temperature or Higher

Primary receptacles include those of glass, metal or plastic. Positive means of ensuring a leak-proof seal, such as heat seal, skirted stopper or metal crimp seal must be provided. If screw caps are used, they must be reinforced with adhesive tape.

(ii) Shipped Refrigerated or Frozen (wet ice, prefrozen packs, Carbon dioxide, solid (dry ice))

Ice or carbon dioxide, solid (dry ice)* must be placed outside the secondary packaging. Interior supports must be provided to secure the secondary packaging in the original position after the ice or carbon dioxide, solid (dry ice) has been dissipated. If ice is used, the packaging must be leak-proof. If carbon dioxide, solid (dry ice) is used, the outer packaging must permit the release of carbon dioxide gas. The primary receptacle must maintain its containment integrity at the temperature of the refrigerant used as well as at the temperature and pressure of air transport to which the receptacle could be subjected if refrigeration were to be lost.

When Carbon dioxide, solid (dry ice) is used as a refrigerant for dangerous goods that require a Shipper's Declaration, the details of the Carbon dioxide, solid (dry ice) must be shown on the Shipper's Declaration. When a Shipper's Declaration is not required, the information as required for the Carbon dioxide, solid (dry ice) must be contained in the "Nature and Quantity of goods" box on the Air Waybill.

*

Carbon dioxide, solid (dry ice) is produced by expanding liquid carbon dioxide into vapor and "snow" in presses that compact the product into blocks. It is used primarily for cooling and due to its very low temperature (about -79°) can cause severe burns to skin upon direct contact. When Carbon dioxide, solid (dry ice) converts (sublimates) directly to gaseous carbon dioxide it takes in heat from its surroundings. The resulting gas is heavier than air and can cause suffocation in confined areas as it displaces air. Venting of packages containing Carbon dioxide, solid (dry ice) is required to avoid pressure build-up. (IATA Dangerous Goods Regulations 1996, p. 591).

(iii) Shipped in Liquid Nitrogen

Primary receptacles must be heat-sealed. Plastic capable of withstanding very low temperatures must be used instead of glass receptacles. Secondary packaging must also withstand very low temperatures and in most cases will need to be fitted over individual primary receptacles. IATA requirements for shipment of liquid nitrogen must also be observed (IATA Packing Instruction 202). The primary receptacle must maintain its containment integrity at the temperature of the refrigerant used as well as at the temperature and pressure of air transport to which the receptacles could be subjected if refrigeration were to be lost.

Whatever the intended temperature of shipment, the primary receptacles and secondary packaging must be capable of withstanding without leakage an internal pressure which produces a pressure differential of not less than 95 kPa (0.95 bar; 13.8 lb/in²) in the temperature range of -40°C to +55°C.

(e) Marking and Labelling

Marking

All packages containing infectious substances must be accompanied by two copies of the IATA Shipper's Declaration for dangerous goods and marked durably and legibly on the outside of the package with the following indications:

(i) The Proper Shipping Names of the contents (as defined by the IATA Dangerous Goods Regulations), the technical (scientific) name(s) of the contents, and the appropriate UN identification number.

For infectious substances, the Proper Shipping Names and UN number are either
infectious substance, affecting humans UN 2814 or
infectious substance, affecting animals only UN 2900.

Thus, for example, a package containing a culture of the typhoid bacillus should be marked (in upper case letters):

“INFECTIOUS SUBSTANCE AFFECTING HUMANS (SALMONELLA TYPHI) UN 2814.”

- (ii) The name, address and telephone number of the consignee (the IDA).
- (iii) The name and address of the shipper.
- (iv) Where liquid nitrogen is used as a refrigerant, the upright position of the package must be indicated prominently by arrows, or by using an approved “Package Orientation” label (see below). The wording “KEEP UPRIGHT” must be placed at 120° intervals around the package or on each side. The package must also be clearly marked “DO NOT DROP—HANDLE WITH CARE.”
- (v) Where solid carbon dioxide (dry ice) is used as a refrigerant, the net mass of solid carbon dioxide within the package should be indicated.

Labelling

Packages must carry the appropriate IATA hazard and handling labels, available from freight agents and postal authorities. The hazard label for use on packages containing infectious substances is a square set at 45° with a white background carrying (in black) the international recognized symbol denoting biological hazard, the legend “Infectious substance. In case of damage or leakage immediately notify Public Health Authority,” and the number 6, which indicates the class of dangerous goods (as determined by the UN Committee of Experts) to which infectious substances belong.

In the case of infectious substances having other hazardous properties—for instance, if they are packed with substances like alcohol (flammable) or phenol (poisonous)—the primary hazard label must always be the “infectious substance” label just mentioned, but the greater of any additional hazards must be identified by the appropriate secondary hazard labelling.

Where appropriate, packages should also carry the relevant IATA handling labels, for example, the “Package Orientation” label mentioned in (e), above, or, where the contents exceed 50g or 50ml without exceeding 4kg or 4l (see below), a “Cargo Aircraft Only” label.

Packages should also carry the internationally recognized green customs label, any other labels required by the relevant national government regulations, and should be accompanied by any documentation required by such regulations. Freight agents and/or postal authorities can advise about these.

(f) Shipper’s Declaration

Packages containing infectious substances must be accompanied by two copies of an IATA Shipper’s Declaration for dangerous goods, made out on the official IATA form which can be obtained from freight agents.

The shipper’s declaration must be completed in English, although the English wording may be supplemented by an accurate translation into another language, if required by the States of origin and/or destination.

(g) Limits on Quantity

For packages carried on passenger aircraft, the maximum net quantity of material is 50ml or 50g; for packages carried on cargo aircraft, maximum net quantities are 4kg or 4l.

4. Non-Infectious Substances

(a) Definition

Non-infectious substances are defined as substances which contain neither living pathogenic microorganisms nor living pathogenic viruses.

(b) Packaging

Such substances must be packed in an inner non-porous container with an outer protective container and with absorbent material placed either in the inner container or between the outer and inner container. This material should be of sufficient quantity to absorb, in case of breakage, all the liquid contained, or capable of being formed, in the inner container. Moreover, the contents of the inner as well as the outer container should be packed in such a way as to prevent any movement. For shipments that are to be transported refrigerated or frozen, or in liquid nitrogen, the practices outlined in 3(d)(ii) and (iii), above, must be observed in respect of the coolants. If the inner container (culture vessel) is sealed or tightly stoppered, it must be capable of withstanding the pressure variations noted in 3(d), above.

(c) Labelling

Both the outer container and outer wrapping must bear the name and address of the sender and of the recipient (the IDA) and should be labelled “perishable biological substances.” Internationally recognized violet-colored labels are available for this last purpose from freight agents and postal authorities. Packages should also carry the internationally recognized green customs label, any other labels required by the relevant national government regulations, and should be accompanied by any documentation required by such regulations. Freight agents and/or postal authorities can advise about these.

(d) Limits on Quantity

There are no limits on the quantities of non-infectious substances that may be transported by air.

5. Genetically Modified Microorganisms and Organisms

“Genetically modified microorganism and organism” refers to an organism in which the genetic material has been purposely altered through genetic engineering in a way that does not occur naturally. For the purpose of the IATA Regulations, genetically modified organisms and microorganisms are divided into the following categories:

- genetically modified microorganisms which meet the definition of an infectious substance. They must be classified in Division 6.2 and assigned UN 2814 or UN 2900;
- animals which contain, or are contaminated with, genetically modified microorganisms or organisms that meet the definition of an infectious substance. Their transportation by air is restricted unless exemption is obtained by the States concerned;
- genetically modified organisms, which are known or suspected to be dangerous to humans, animals or the environment. They must not be transported by air unless exempted by the States concerned; their transportation by air is restricted unless exemption is obtained by the States concerned;

- except when authorized for unconditional use by the States of origin, transit and destination, genetically modified microorganisms which do not meet the definition of infectious substances but which are capable of altering animals, plants or microbiological substances in a way not normally the result of natural reproduction must be classified in Class 9 and assigned UN 3245.

6. Plant Pathogens

The classification of plant pathogens varies for different countries, as the criteria are not only the pathogenicity or virulence of a species or strain, but also its occurrence in a particular country and the availability of possible hosts. Many countries require import permits for certain species. As regards Europe, see “Commission Directive 92/103/EEC of 1 December 1992 amending Annexes I-IV of Council Directive 77/93/EEC on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community.”

7. Toxinogenic Microorganisms

Certain toxin producing bacteria and fungi are considered as a potential danger for public health. In different countries import and/or export restrictions may exist.

8. Prevention of Biological Warfare Proliferation

The prevention of uncontrolled export of certain biological materials is regulated in Europe by the “Council Regulation EC no 3381/94 on the Control of Exports of Dual-Use Goods from the Community of 19th December 1994,” effective from July 1, 1995. The said Regulation controls the export of biological materials pathogenic to humans, animals or plants, of toxins and of genetically modified microorganisms.

The list of biological materials is Annex I of the “Council Decision of 19th December 1994 on the Joint Action adopted by the Council on the Basis of Article J.3 of the Treaty on European Union concerning the Control of Export of Dual-Use Goods from the Community (94/942/PESC) (Publication L367/8/CEC of 31.12.1994).” “Council Regulation 3381/94 is amended by Council Regulation (EC) no 837/95 of 10th April 1995 (Publication L90/1 of 21.04.1995).” Council Decision 94/942/PESC is amended by “Council Decision of 10th April 1995 (95/127/PESC)(Publication L90/2 of 21.04.1995).”

The transport of such material is also regulated by national laws.

[End of Appendix 4]

REQUIRED STANDARDS OF PACKAGING FOR THE TRANSPORT OF MICROORGANISMS BY AIR*

1. General

If cultures of microorganisms are to be transported by air, they must be packaged and identified by display labelling and certification in such a way as to satisfy the regulations of the International Air Transport Association (IATA) for the shipping of perishable biological substances. These regulations apply whether the microorganisms are to be sent by air freight or by air mail, and packages not complying are liable to be refused transit by the carrier or to be stopped and destroyed by customs or postal authorities.

This Appendix is intended only as a general guide to the required standards of packaging for the transport of microorganisms by air. The actual regulations themselves are updated regularly by IATA and there are slight variations in the detailed requirements of individual air operators and of individual countries. Therefore, senders should check with their own freight handling agents and/or postal authorities as appropriate for exact and up-to-date information.

2. Categorization of Microorganisms

For the purposes of air transport regulations, microorganisms fall into two broad categories, depending on their pathogenicity: infectious substances (infectious perishable biological substances or IPBS) and non-infectious substances (non-infectious perishable biological substances or non-infectious PBS).

3. Infectious Substances**

(a) Definition

Infectious substances are subject to the IATA Dangerous Goods Regulations and are defined therein as:

“substances containing viable microorganisms or their toxins which are known, or suspected, to cause disease in animals or humans.”

*

This Appendix takes into account information contained in the brochure “Shipping of Infectious, Non-Infectious and Genetically Modified Biological Material – International Regulations,” edited by the Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH (DSMZ), Braunschweig, Germany.

**

Much of the information relating to the transport of infectious substances has been taken directly from the IATA Dangerous Goods Regulations by kind permission of the International Air Transport Association, Montreal, Canada.

(b) Packaging

Packages containing infectious substances must comply both with the IATA General Packing Requirements, which apply to all dangerous goods, and with the specific requirements for packing infectious substances. The General Packing Requirements, which include details of the minimum specifications and tolerances of packaging systems and materials, are given in paragraphs 5.0.8 to 5.0.23 of the IATA Dangerous Goods Regulations. These requirements are intended to ensure, inter alia, that packages and their closures will withstand the normal stresses of air transport (vibration, changes in pressure, temperature, humidity, etc.) without leakage; that they are not affected chemically or physically by their contents; that materials which react dangerously with each other are not packaged together; and that infectious substances are packaged separately from other dangerous goods.

The specific requirements for the packaging of infectious substances are laid down in Packing Instruction 602 of the IATA Dangerous Goods Regulations. Shipments must be packaged so that they arrive at their destination in good condition and do not present any hazard to humans or animals during transit. Packaging must include the following elements:

- (i) Inner packagings comprising:
 - a watertight primary receptacle (culture vessel);
 - a watertight secondary packaging;
 - an absorbent material which must be placed between the primary receptacle and the secondary packaging. If several primary receptacles are placed in a single secondary packaging they must be wrapped individually to ensure that contact between them is prevented. The absorbent material (e.g., cotton wool, cellulose wadding, etc.) must be sufficient to absorb the entire contents of all primary receptacles.
- (ii) An outer packaging of sufficient strength to meet the performance tests specified by the IATA Regulations. These tests are designed to ensure that the package will withstand the stresses of normal handling during transit and will not be damaged by accidental dropping, crushing, etc.

Packages sent as air freight must be at least 100mm in the smallest overall external dimension.

All packages containing infectious substances must contain, between the secondary and outer packagings, an itemized list of contents and must be accompanied by two copies of the IATA Shipper's Declaration for dangerous goods, made out on the official IATA form which can be obtained from freight agents.

With a few exceptions, infectious substances can and must be packaged according to the following guidelines:

(c) Lyophilized Substances

Primary receptacles include flame-sealed glass ampoules or rubber stoppered glass vials fitted with metal seals. Dried or freeze-dried non-infectious microbial cultures may not be considered to be perishable. Therefore, such cultures may be shipped by mail to any country as far as no general import restrictions exist. Infectious, non-perishable cultures, however, should be handled in any case like infectious perishable microbial cultures.

(d) Liquid or Solid Substances

(i) Shipped at Ambient Temperature or Higher

Primary receptacles include those of glass, metal or plastic. Positive means of ensuring a leak-proof seal, such as heat seal, skirted stopper or metal crimp seal must be provided. If screw caps are used, they must be reinforced with adhesive tape.

(ii) Shipped Refrigerated or Frozen (wet ice, prefrozen packs, Carbon dioxide, solid (dry ice))

Ice or carbon dioxide, solid (dry ice)* must be placed outside the secondary packaging. Interior supports must be provided to secure the secondary packaging in the original position after the ice or carbon dioxide, solid (dry ice) has been dissipated. If ice is used, the packaging must be leak-proof. If carbon dioxide, solid (dry ice) is used, the outer packaging must permit the release of carbon dioxide gas. The primary receptacle must maintain its containment integrity at the temperature of the refrigerant used as well as at the temperature and pressure of air transport to which the receptacle could be subjected if refrigeration were to be lost.

When Carbon dioxide, solid (dry ice) is used as a refrigerant for dangerous goods that require a Shipper's Declaration, the details of the Carbon dioxide, solid (dry ice) must be shown on the Shipper's Declaration. When a Shipper's Declaration is not required, the information as required for the Carbon dioxide, solid (dry ice) must be contained in the "Nature and Quantity of goods" box on the Air Waybill.

*

Carbon dioxide, solid (dry ice) is produced by expanding liquid carbon dioxide into vapor and "snow" in presses that compact the product into blocks. It is used primarily for cooling and due to its very low temperature (about -79°) can cause severe burns to skin upon direct contact. When Carbon dioxide, solid (dry ice) converts (sublimates) directly to gaseous carbon dioxide it takes in heat from its surroundings. The resulting gas is heavier than air and can cause suffocation in confined areas as it displaces air. Venting of packages containing Carbon dioxide, solid (dry ice) is required to avoid pressure build-up. (IATA Dangerous Goods Regulations 1996, p. 591).

(iii) Shipped in Liquid Nitrogen

Primary receptacles must be heat-sealed. Plastic capable of withstanding very low temperatures must be used instead of glass receptacles. Secondary packaging must also withstand very low temperatures and in most cases will need to be fitted over individual primary receptacles. IATA requirements for shipment of liquid nitrogen must also be observed (IATA Packing Instruction 202). The primary receptacle must maintain its containment integrity at the temperature of the refrigerant used as well as at the temperature and pressure of air transport to which the receptacles could be subjected if refrigeration were to be lost.

Whatever the intended temperature of shipment, the primary receptacles and secondary packaging must be capable of withstanding without leakage an internal pressure which produces a pressure differential of not less than 95 kPa (0.95 bar; 13.8 lb/in²) in the temperature range of -40°C to +55°C.

(e) Marking and Labelling

Marking

All packages containing infectious substances must be accompanied by two copies of the IATA Shipper's Declaration for dangerous goods and marked durably and legibly on the outside of the package with the following indications:

(i) The Proper Shipping Names of the contents (as defined by the IATA Dangerous Goods Regulations), the technical (scientific) name(s) of the contents, and the appropriate UN identification number.

For infectious substances, the Proper Shipping Names and UN number are either
infectious substance, affecting humans UN 2814 or
infectious substance, affecting animals only UN 2900.

Thus, for example, a package containing a culture of the typhoid bacillus should be marked (in upper case letters):

“INFECTIOUS SUBSTANCE AFFECTING HUMANS (SALMONELLA TYPHI) UN 2814.”

- (ii) The name, address and telephone number of the consignee (the IDA).
- (iii) The name and address of the shipper.
- (iv) Where liquid nitrogen is used as a refrigerant, the upright position of the package must be indicated prominently by arrows, or by using an approved “Package Orientation” label (see below). The wording “KEEP UPRIGHT” must be placed at 120° intervals around the package or on each side. The package must also be clearly marked “DO NOT DROP—HANDLE WITH CARE.”
- (v) Where solid carbon dioxide (dry ice) is used as a refrigerant, the net mass of solid carbon dioxide within the package should be indicated.

Labelling

Packages must carry the appropriate IATA hazard and handling labels, available from freight agents and postal authorities. The hazard label for use on packages containing infectious substances is a square set at 45° with a white background carrying (in black) the international recognized symbol denoting biological hazard, the legend “Infectious substance. In case of damage or leakage immediately notify Public Health Authority,” and the number 6, which indicates the class of dangerous goods (as determined by the UN Committee of Experts) to which infectious substances belong.

In the case of infectious substances having other hazardous properties—for instance, if they are packed with substances like alcohol (flammable) or phenol (poisonous)—the primary hazard label must always be the “infectious substance” label just mentioned, but the greater of any additional hazards must be identified by the appropriate secondary hazard labelling.

Where appropriate, packages should also carry the relevant IATA handling labels, for example, the “Package Orientation” label mentioned in (e), above, or, where the contents exceed 50g or 50ml without exceeding 4kg or 4l (see below), a “Cargo Aircraft Only” label.

Packages should also carry the internationally recognized green customs label, any other labels required by the relevant national government regulations, and should be accompanied by any documentation required by such regulations. Freight agents and/or postal authorities can advise about these.

(f) Shipper’s Declaration

Packages containing infectious substances must be accompanied by two copies of an IATA Shipper’s Declaration for dangerous goods, made out on the official IATA form which can be obtained from freight agents.

The shipper’s declaration must be completed in English, although the English wording may be supplemented by an accurate translation into another language, if required by the States of origin and/or destination.

(g) Limits on Quantity

For packages carried on passenger aircraft, the maximum net quantity of material is 50ml or 50g; for packages carried on cargo aircraft, maximum net quantities are 4kg or 4l.

4. Non-Infectious Substances

(a) Definition

Non-infectious substances are defined as substances which contain neither living pathogenic microorganisms nor living pathogenic viruses.

(b) Packaging

Such substances must be packed in an inner non-porous container with an outer protective container and with absorbent material placed either in the inner container or between the outer and inner container. This material should be of sufficient quantity to absorb, in case of breakage, all the liquid contained, or capable of being formed, in the inner container. Moreover, the contents of the inner as well as the outer container should be packed in such a way as to prevent any movement. For shipments that are to be transported refrigerated or frozen, or in liquid nitrogen, the practices outlined in 3(d)(ii) and (iii), above, must be observed in respect of the coolants. If the inner container (culture vessel) is sealed or tightly stoppered, it must be capable of withstanding the pressure variations noted in 3(d), above.

(c) Labelling

Both the outer container and outer wrapping must bear the name and address of the sender and of the recipient (the IDA) and should be labelled “perishable biological substances.” Internationally recognized violet-colored labels are available for this last purpose from freight agents and postal authorities. Packages should also carry the internationally recognized green customs label, any other labels required by the relevant national government regulations, and should be accompanied by any documentation required by such regulations. Freight agents and/or postal authorities can advise about these.

(d) Limits on Quantity

There are no limits on the quantities of non-infectious substances that may be transported by air.

5. Genetically Modified Microorganisms and Organisms

“Genetically modified microorganism and organism” refers to an organism in which the genetic material has been purposely altered through genetic engineering in a way that does not occur naturally. For the purpose of the IATA Regulations, genetically modified organisms and microorganisms are divided into the following categories:

- genetically modified microorganisms which meet the definition of an infectious substance. They must be classified in Division 6.2 and assigned UN 2814 or UN 2900;
- animals which contain, or are contaminated with, genetically modified microorganisms or organisms that meet the definition of an infectious substance. Their transportation by air is restricted unless exemption is obtained by the States concerned;
- genetically modified organisms, which are known or suspected to be dangerous to humans, animals or the environment. They must not be transported by air unless exempted by the States concerned; their transportation by air is restricted unless exemption is obtained by the States concerned;

- except when authorized for unconditional use by the States of origin, transit and destination, genetically modified microorganisms which do not meet the definition of infectious substances but which are capable of altering animals, plants or microbiological substances in a way not normally the result of natural reproduction must be classified in Class 9 and assigned UN 3245.

6. Plant Pathogens

The classification of plant pathogens varies for different countries, as the criteria are not only the pathogenicity or virulence of a species or strain, but also its occurrence in a particular country and the availability of possible hosts. Many countries require import permits for certain species. As regards Europe, see “Commission Directive 92/103/EEC of 1 December 1992 amending Annexes I-IV of Council Directive 77/93/EEC on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community.”

7. Toxinogenic Microorganisms

Certain toxin producing bacteria and fungi are considered as a potential danger for public health. In different countries import and/or export restrictions may exist.

8. Prevention of Biological Warfare Proliferation

The prevention of uncontrolled export of certain biological materials is regulated in Europe by the “Council Regulation EC no 3381/94 on the Control of Exports of Dual-Use Goods from the Community of 19th December 1994,” effective from July 1, 1995. The said Regulation controls the export of biological materials pathogenic to humans, animals or plants, of toxins and of genetically modified microorganisms.

The list of biological materials is Annex I of the “Council Decision of 19th December 1994 on the Joint Action adopted by the Council on the Basis of Article J.3 of the Treaty on European Union concerning the Control of Export of Dual-Use Goods from the Community (94/942/PESC) (Publication L367/8/CEC of 31.12.1994).” “Council Regulation 3381/94 is amended by Council Regulation (EC) no 837/95 of 10th April 1995 (Publication L90/1 of 21.04.1995).” Council Decision 94/942/PESC is amended by “Council Decision of 10th April 1995 (95/127/PESC)(Publication L90/2 of 21.04.1995).”

The transport of such material is also regulated by national laws.

[End of Appendix 4]

WIPO



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WORLD INTELLECTUAL PROPERTY ORGANIZATION
GENEVA

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**BUDAPEST TREATY ON THE INTERNATIONAL
RECOGNITION OF THE DEPOSIT OF MICROORGANISMS
FOR THE PURPOSES OF PATENT PROCEDURE**

Note by the International Bureau

I. INTRODUCTION

1. The Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (hereinafter referred to as the “Treaty”) was adopted by the Budapest Diplomatic Conference on April 28, 1977, and it entered into force on August 19, 1980. The Conference also adopted Regulations under the Treaty.

2. On March 1, 1999, the following 45 States were party to the Treaty: Australia, Austria, Belgium, Bulgaria, Canada, China, Cuba, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Israel, Italy, Japan, Latvia, Liechtenstein, Lithuania, Monaco, Netherlands, Norway, Philippines, Poland, Portugal, Republic of Korea, Republic of Moldova, Russian Federation, Singapore, Slovakia, Slovenia, South Africa, Spain, Sweden, Switzerland, Tajikistan, Trinidad and Tobago, Turkey, Ukraine, United Kingdom, United States of America, Yugoslavia.

II. SUMMARY AND MAIN ADVANTAGES OF THE TREATY

Background

3. Disclosure of the invention is a generally recognized requirement for the grant of patents. Normally, an invention is disclosed by means of a written description. Where an invention involves a microorganism, or the use of a microorganism, which is not available to the public, such a description is not sufficient for disclosure. That is why in the patent procedure of an increasing number of countries it is necessary not only to file a written description but also to deposit, with a specialized institution, a sample of the microorganism. Patent offices are not equipped to handle microorganisms, whose preservation requires special expertise and equipment to keep them viable, to protect them from contamination and to protect health or the environment from contamination. Such preservation is costly. The furnishing of samples also requires specialized expertise and equipment.

4. When protection is sought in several countries for an invention involving a microorganism or the use of a microorganism, the complex and costly procedures of the deposit of the microorganism would have to be repeated in each of those countries. It was in order to eliminate or reduce such multiplication, in order to enable one deposit to serve the purpose of all the deposits which would otherwise be necessary, that the Treaty was concluded.

Summary of the Treaty and the Regulations

5. Substantive Provisions. The main feature of the Treaty is that a Contracting State which allows or requires the deposit of microorganisms for the purposes of patent procedure must recognize, for such purposes, the deposit of a microorganism with any “international depositary authority” (Article 3(1)(a)), irrespective of whether such authority is on or outside the territory of the said State. In other words, one deposit, with one international depositary authority, will suffice for the purposes of patent procedure before the national patent offices (called “industrial property offices” in the Treaty) of all of the Contracting States and before any regional patent organization if such a regional organization declares that it recognizes the effects of the Treaty (Article 9(1)). The European Patent Organisation (EPO) and the African Regional Industrial Property Organization (ARIPO) have made such a declaration.

6. What the Treaty calls an “international depositary authority” is a scientific institution—typically a “culture collection”—which is capable of storing microorganisms. Such an institution acquires the status of “international depositary authority” through the furnishing, by one of the Contracting States, of assurances to the Director General of WIPO to the effect that the said institution complies and will continue to comply with certain requirements (Article 6(1)), including, in particular, that it will be available, for the purposes of the deposit of microorganisms, to any “depositor” (person, firm, etc.), that it will accept and store the deposited microorganisms and that it will furnish samples thereof to anyone entitled to such samples but to no one else. The said assurances may be furnished also by certain intergovernmental industrial property organizations (see Article 9(1)(a)). The European

Patent Organisation has furnished the said assurances. To date, 31 depositary institutions have acquired the status of international depositary authority.*

7. The Regulations contain detailed provision (Rule 11) on who is entitled—and when—to receive samples of the deposited microorganism. The depositor himself has a right to a sample at any time (Rule 11.2(i)). He may authorize any third party (authority, natural person, legal entity) to ask for a sample and such a third party will receive a sample upon producing such an authorization (Rule 11.2(ii)). Any “interested” industrial property office to which the Treaty applies may ask for a sample and will receive one; an industrial property office will mainly be regarded as “interested” where the microorganism is needed for the purposes of patent procedure before the said office (Rule 11.1). Any other party may obtain a sample if an industrial property office to which the Treaty applies certifies that, under the applicable law, such a party has the right to a sample of the given microorganism; the elements of the certification are provided for in detail to ensure that the maximum extent of caution will be exercised by the industrial property office before it issues a certification (Rule 11.3(a)).

* Australia: Australian Government Analytical Laboratories (AGAL);
Belgium: Belgian Coordinated Collections of Microorganisms (BCCM™);
Bulgaria: National Bank for Industrial Microorganisms and Cell Cultures (NBIMCC);
Canada: Bureau of Microbiology at Health Canada (BMHC);
China: China Center for Type Culture Collection (CCTCC); China General Microbiological Culture Collection Center (CGMCC);
Czech Republic: Czech Collection of Microorganisms (CCM);
France: Collection nationale de cultures de micro-organismes (CNCM);
Germany: DSMZ--Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH (DSMZ);
Hungary: National Collection of Agricultural and Industrial Microorganisms (NCAIM);
Italy: Advanced Biotechnology Center (ABC); Collection of Industrial Yeasts DBVPG;
Japan: National Institute of Bioscience and Human-Technology (NIBH);
Latvia: Microbial Strain Collection of Latvia (MSCL);
Netherlands: Centraalbureau voor Schimmelcultures (CBS);
Republic of Korea: Korean Cell Line Research Foundation (KCLRF); Korean Culture Center of Microorganisms (KCCM); Korean Collection for Type Cultures (KCTC);
Russian Federation: All-Russian Scientific Centre of Antibiotics (VNIIA);
Russian Collection of Microorganisms (VKM); Russian National Collection of Industrial Microorganisms (VKPM), GNII Genetika;
Slovakia: Culture Collection of Yeasts (CCY);
Spain: Colección Española de Cultivos Tipo (CECT);
United Kingdom: Culture Collection of Algae and Protozoa (CCAP);
European Collection of Cell Cultures (ECACC); International Mycological Institute (IMI);
National Collection of Type Cultures (NCTC); National Collection of Yeast Cultures (NCYC);
National Collections of Industrial and Marine Bacteria Ltd. (NCIMB);
United States of America: Agricultural Research Service Culture Collection (NRRL);
American Type Culture Collection (ATCC).

8. The Treaty and the Regulations also contain provisions allowing for what is called a “new” deposit where samples of the originally deposited microorganisms can no longer be furnished (Article 4); permitting the termination or limitation of the status of international depositary authority where the said authority does not or does no longer fully comply with its assumed duties (Article 8); requiring that all microorganisms deposited with an international depositary authority be transferred to another such authority if the former is about to cease functioning as such (Rule 5.1); regulating the content of the receipt that each international depositary authority is required to give to the depositor for the deposited microorganism (Rule 7); providing for the testing of the viability of the deposited microorganisms and the issuance of viability statements (Rule 10); allowing the international depositary authority to charge a fee for each deposit, that fee covering the minimum 30 years during which the deposited microorganism must be stored (Rules 9 and 12); providing for a special status and a special role for certain intergovernmental organizations (Article 9).

9. Administrative Provisions. The States party to the Treaty constitute a Union (“the Budapest Union”) (Article 1). The Budapest Union has an Assembly consisting of the States members of the said Union, the main tasks of the Assembly being to deal with all matters concerning the maintenance and development of the Union and the implementation of the Treaty (Article 10(2)), including the powers to amend certain provisions of the Treaty (Article 14), to amend the Regulations (Article 12(3)) and to take away or limit the status of any given international depositary authority (Article 8(1)). Certain administrative tasks are entrusted to the International Bureau of WIPO (Article 11). The possibility of amending the Treaty in revision conferences is also provided for (Article 13).

Main Advantages of the Treaty

10. By acknowledging the multiple legal effect of a single deposit, the Treaty makes the patent procedure simpler and the patenting more attractive in the States party to the Treaty and reduces the biosafety risk of transferring microorganisms into several countries. The Treaty is primarily advantageous to the depositor who is an applicant for patents in several countries; the deposit of a microorganism under the procedures provided for in the Treaty will save him money and strengthen his security. It will save him money because, instead of depositing the microorganism in each and every country in which he files a patent application referring to that microorganism, he can deposit it only once, with one depositary, with the consequence that in all but one of the countries in which he seeks protection he will save the fees and costs that deposits would otherwise have entailed. In most cases, there will be at least one international depositary authority in the country of the depositor, which means that he will deal with an authority which is close to him, with which he can deal in his own language, to which he can pay the fees in his own currency and which he may even know from personal experience; in other words, he will be able to avoid dealing with distant authorities, in foreign currencies and in foreign languages. He will probably have a natural trust in the authority carefully preserving the viability of the deposited microorganism and furnishing samples only to those who are entitled to receive them.

11. The security of the depositor is increased by the fact that, for an institution to become an international depositary authority, solemn assurances as to the seriousness and continued existence of that institution must be given; such assurances must be given by a State or by an intergovernmental organization and they are addressed to all the member States of the Budapest Union. Consequently, it may be expected that the assurances will be strictly respected, all the more so since, if they are not so respected, the member States may take away from the defaulting institution the status of international depositary authority.

12. It is to be noted that the Treaty does not require the establishment of an International Depositary Authority in a Contracting State.

13. The Treaty contains no financial provisions. No State can be requested to pay contributions to the International Bureau of WIPO on account of its membership in the Budapest Union.

III. RATIFICATION OF AND ACCESSION TO THE TREATY

14. Conditions. Any State member of the International (Paris) Union for the Protection of Industrial Property may become party to the Budapest Treaty (Article 15(1)).

15. The States that have signed the Treaty may become party to it by depositing an instrument of ratification. Those that have not signed it may become party to it by depositing an instrument of accession.

16. Instruments of ratification or accession are to be deposited with the Director General of WIPO (Article 15).

17. A model instrument of accession is attached to this Note (see Annex).

[Annex follows]

MODEL

INSTRUMENT OF ACCESSION TO THE BUDAPEST TREATY
ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT
OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

(to be deposited with the Director General of WIPO in Geneva)

The Government of [name of State] hereby declares that [name of State] accedes to the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, done at Budapest on April 28, 1977, and amended on September 26, 1980.

Done at, on, 199..

Signature^{*}

(seal)

* The instrument should be signed by the Head of State, the Head of Government or the Minister for Foreign Affairs.